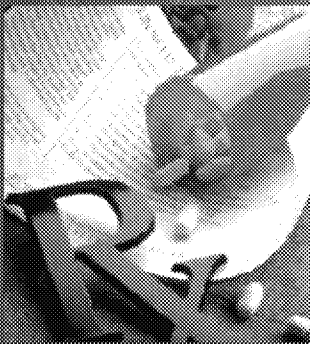


# **EXHIBIT 13**



The United States Department of Justice  
**Drug Enforcement Administration**



# *Prescription Drug Trafficking Trends, Synthetic Drugs and Methamphetamine*

American Society of Interventional Pain Physicians

Crystal City, Virginia  
June 9, 2012

**Joseph Rannazzisi**  
**Deputy Assistant Administrator**  
**DEA Office of Diversion Control**



# Disclosure Information

I have no financial relationships to disclose

AND

I will not discuss off-label use and/or  
investigational drug use in my presentation

- **Responding to America's Prescription Drug Abuse Crisis**

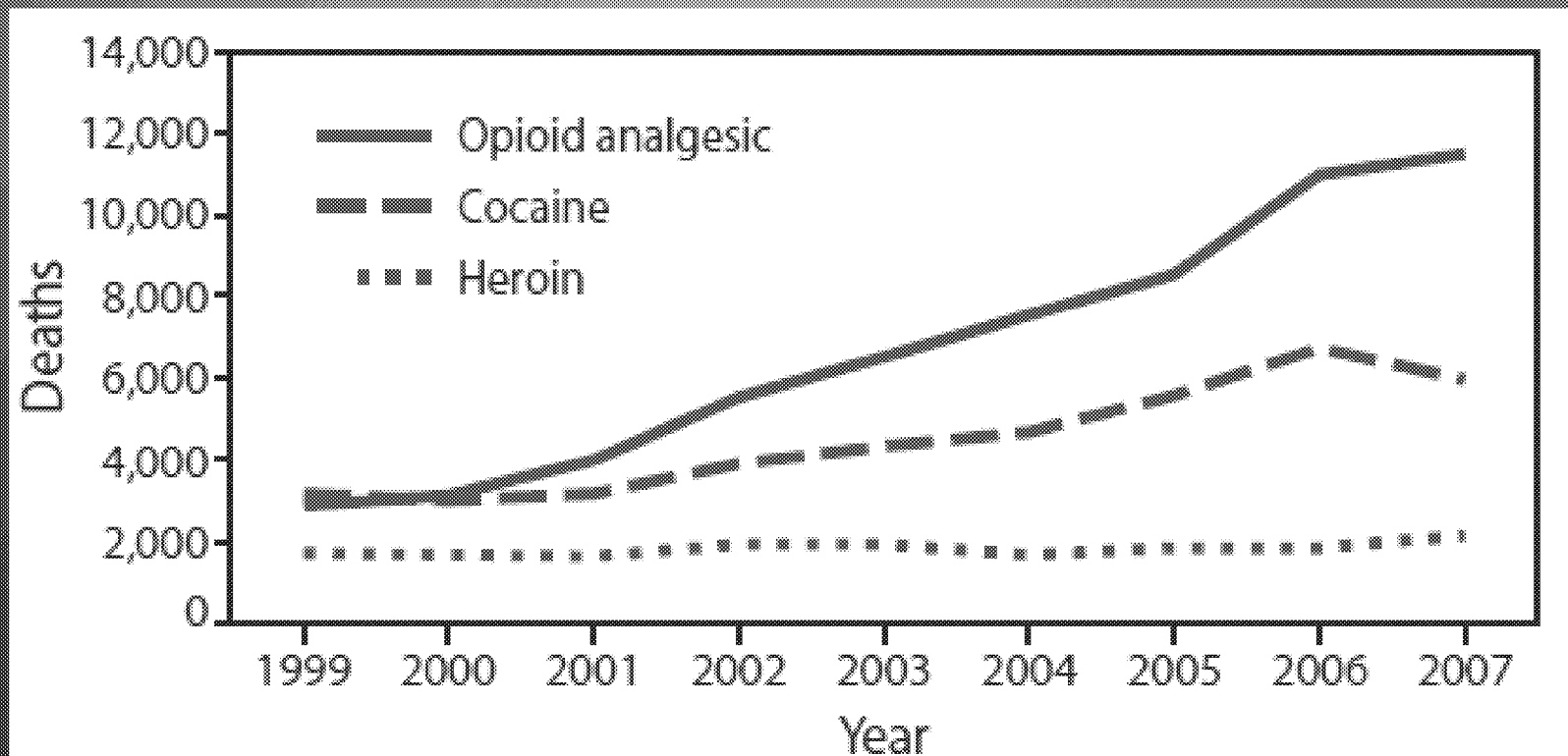
- *“When Two Addictions Collide”*



“In 2007, approximately 27,000 unintentional drug overdose deaths occurred in the United States, one death every 19 minutes. Prescription drug abuse is the fastest growing drug problem in the United States.”\*

\*CDC Grand Rounds: Prescription Drug Overdoses-a U.S. Epidemic  
Morbidity and Mortality Weekly Report January 13, 2012/Vol.61/No.1

## Number of unintentional drug overdose deaths involving opioid analgesics, cocaine, and heroin — United States, 1999–2007



**Source:** National Vital Statistics System.  
Multiple cause of death dataset. Available at  
<http://www.cdc.gov/nchs/nvss.htm>



# Legend Drugs v. Controlled Substances

# Prescription Requirements

	Schedule II	Schedule III	Schedule IV	Schedule V
Written	Yes	Yes	Yes	Yes
Oral	Emergency Only*	Yes	Yes	Yes
Facsimile	Yes**	Yes	Yes	Yes
Refills	No	Yes#	Yes#	Yes#
Partial Fills	Yes***	Yes	Yes	Yes


\* Must be reduced in writing, and followed by sign, hard copy of the prescription.

\*\* A signed, hard copy of the prescription must be presented before the medication is dispensed.

\*\*\* 72 hour time limitation.

# With medical authorization, up to 5 in 6 months.



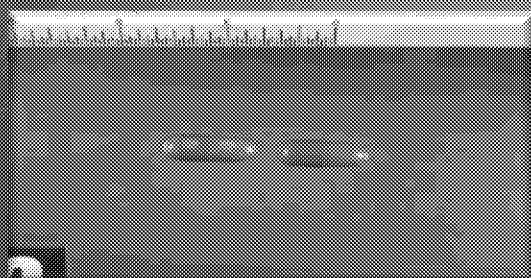


Prescription drug  
epidemic?  
How did we get to this  
point?

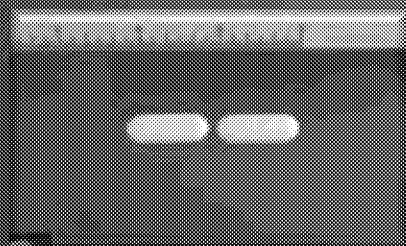
# The 1960/70s/80s



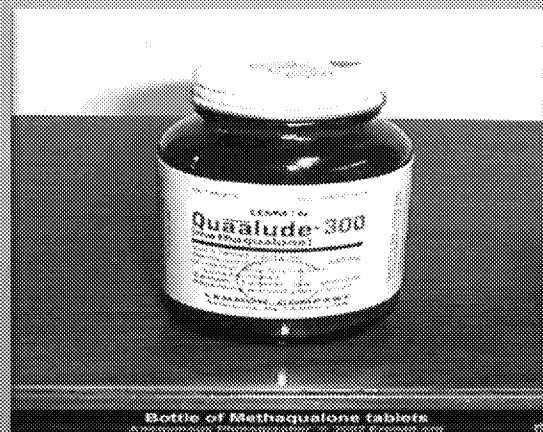
Uppers - Dexedrine



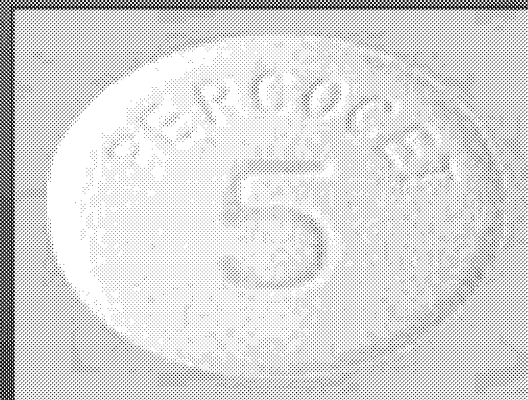
Downers - Seconal



Meprobamate



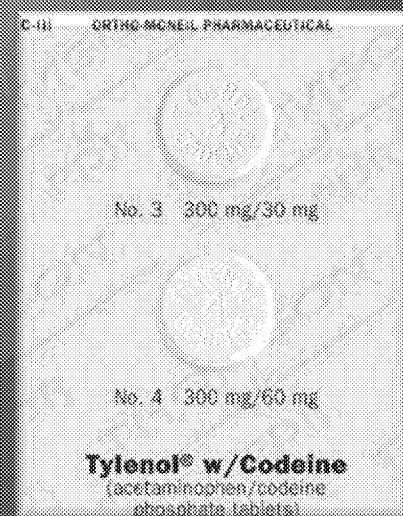
Hydromorphone



Oxycodone/APAP



"Ts and Blues"

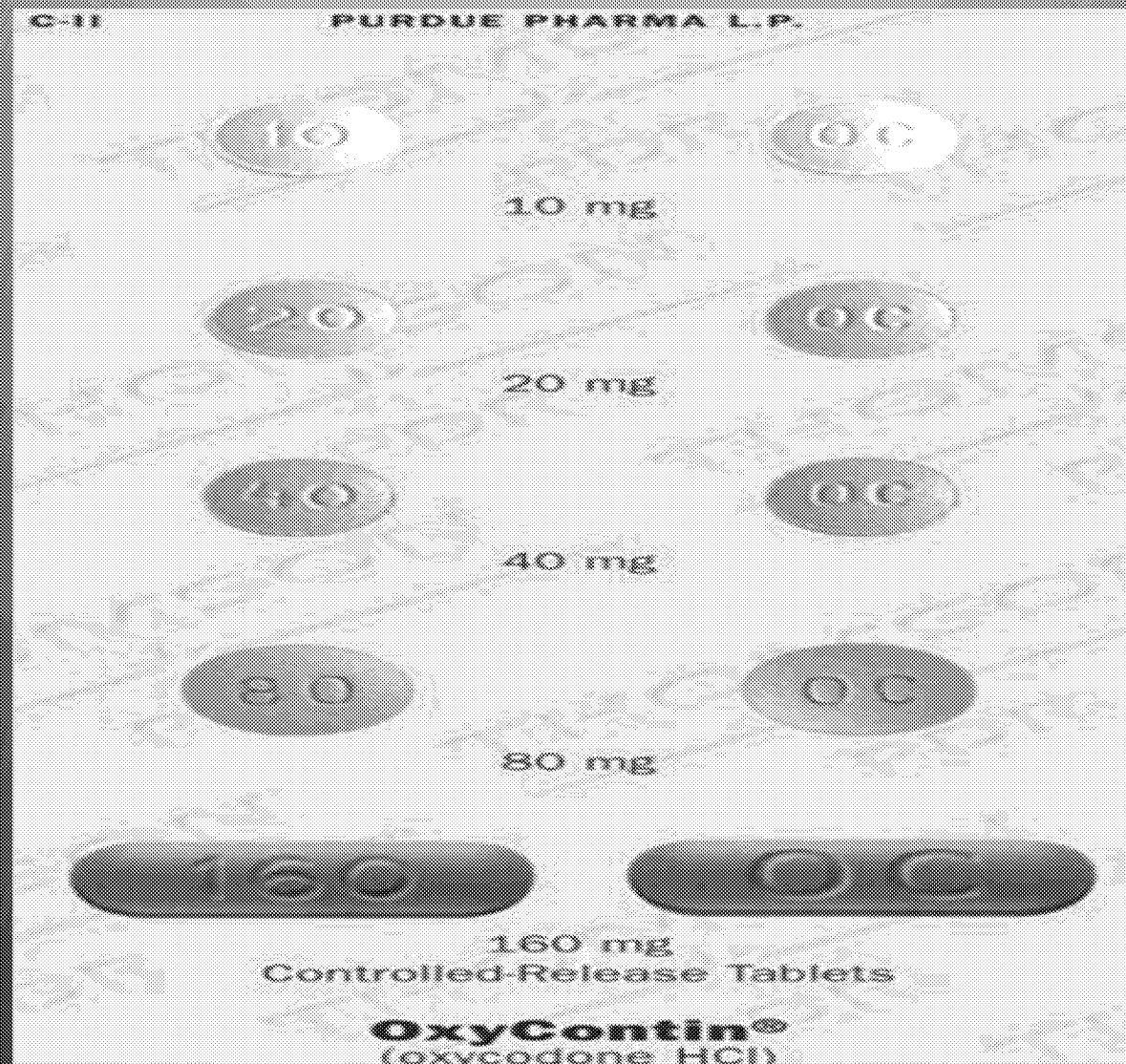


"Fours and Doors"



# The 1990s

## OxyContin



# Inadequate Pain Control



# Commonly Abused Controlled

## Pharmaceuticals

Carisoprodol

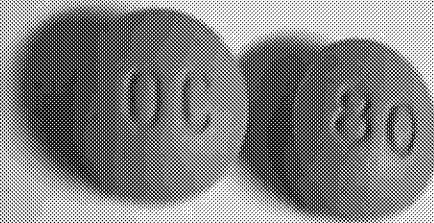


C-IV as of 1/11/2012

**CYCLOBENZAPRINE  
(FLEXERIL)**



**Hydrocodone**



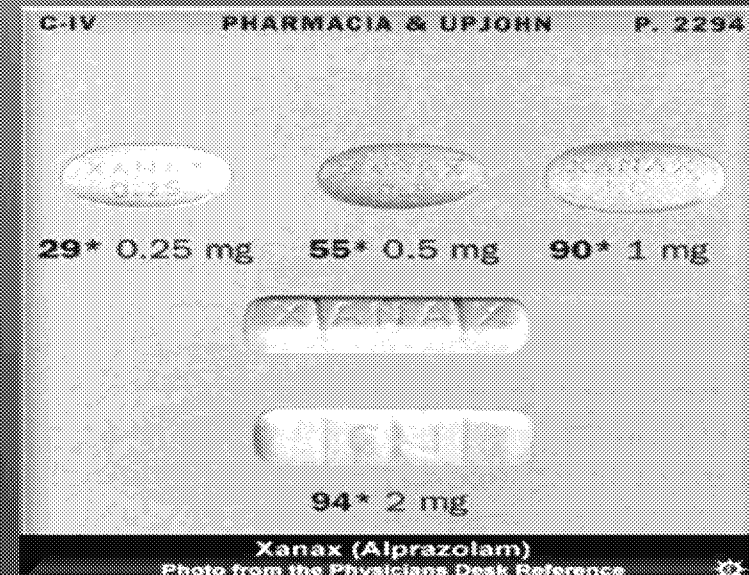
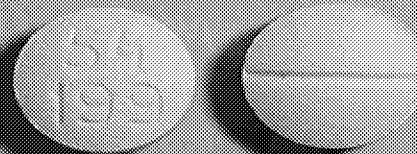
OxyContin 80mg



Oxymorphone



**Oxycodone 30 mg**



**Xanax (Alprazolam)**

Photo from the Physicians Desk Reference

**Alprazolam**

# Direct to consumer advertising



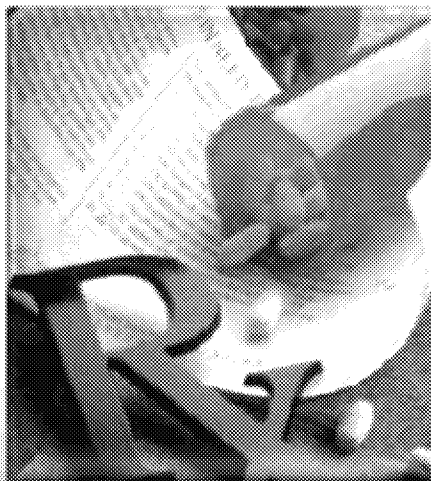
# The Perfect Storm

- **Industry is producing a wider variety of controlled substance pharmaceuticals and practitioners are prescribing more.**
- **Use of Medicare / Medicaid or insurance to fund drug habits**
- **Information / Electronic era**

— Orlando, FL • April 10-12, 2012 —  
**NATIONAL  
RX DRUG ABUSE  
SUMMIT**  
NationalDrugAbuseSummit.org

# The Controlled Substances Act

## Checks and Balances



— Orlando, FL • April 10-12, 2012 —  
**NATIONAL  
RX DRUG ABUSE  
SUMMIT**  
NationalDrugAbuseSummit.org

# The Flow of Pharmaceuticals

QUOTAS

21 USC 823(c)(1)  
21 USC 823(d)(1)  
21 CFR 1301.71

21 USC 823(b)(1)  
21 USC 823(e)(1)  
21 CFR 1301.71  
21 CFR 1301.74  
(Suspicious Orders)

2012, FL • April 10-12, 2012  
NATIONAL  
RX DRUG ABUSE  
SUMMIT  
National Drug Abuse Summit Co.

Raw Material

Importers

Imp - Manufacturers

Manufacturers

Dosage Form  
Manufacturers

Dosage Form  
Manufacturers

Smaller Distributors

Wholesalers - Distributors

Hospitals

Pharmacies

Physicians  
(Rx and drugs)

NTPs

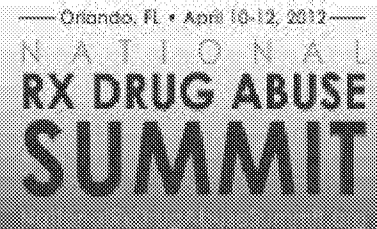
21 CFR 1306.04

PATIENTS

# Checks and Balances of the CSA and the Regulatory Scheme

- Distributors of controlled substances

*“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” (21 CFR § 1301.74)*





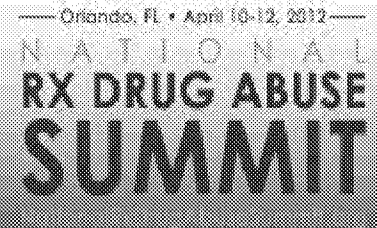
# Checks and Balances

## Under the CSA

- Practitioners

*“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.”* (21 CFR § 1306.04(a))

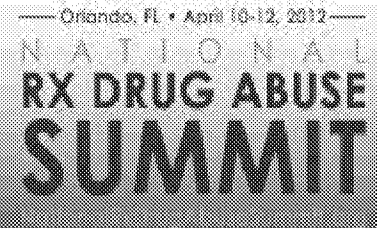
*United States v Moore* 423 US 122 (1975)



# Checks and Balances Under the CSA

- Pharmacists – The Last Line of Defense

*“The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” (21 CFR § 1306.04(a))*



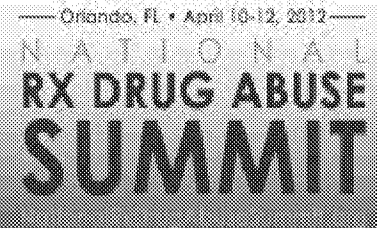
**What can happen when these  
checks and balances collapse  
and diversion occurs?**

— Orlando, FL • April 10-12, 2012 —  
NATIONAL  
RX DRUG ABUSE  
SUMMIT  
National Rx Abuse Summit, Inc.



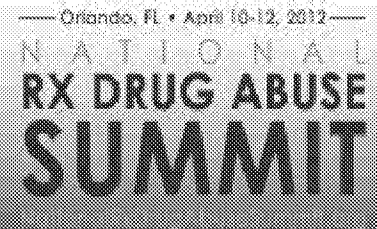
# Large-Scale Diversion

- In 2009, the average purchase for all oxycodone products for all pharmacies in US – 63,294 d.u.
- In 2010, the average was – 69,449 d.u.
- In 2009, the average purchase for all oxycodone products for the top 100 pharmacies in Florida – 1,226,460 d.u.
- In 2010, the average was – 1,261,908 d.u.



# Purchases of Oxycodone 30mg

- In 2009, 44% of all oxycodone 30mg products were distributed to Florida
- In 2010, 43% of all oxycodone 30mg products were distributed to Florida



# Drug Dealers Masquerading as Doctors

## Paul Volkman, Chicago Doctor, Gets 4 Life Terms In Drug Overdose Case



ANDREW WELSH-HUGGINS 02/14/12 06:45 PM ET Associated Press

COLUMBUS, Ohio — A Chicago doctor who prosecutors say dispensed more of the powerful painkiller oxycodone from 2003 to 2005 than any other physician in the country was sentenced Tuesday to four life terms in the overdose deaths of four patients.

Dr. Paul Volkman made weekly trips from Chicago to three locations in Portsmouth in southern Ohio and one in Chillicothe in central Ohio before federal investigators shut down the operations in 2006, prosecutors said. He was sentenced in federal court in Cincinnati.

"This criminal conduct had devastating consequences to the community Volkman was supposed to serve," Assistant U.S. Attorneys Adam Wright and Tim Oakley said in a court filing ahead of Tuesday's hearing.

"Volkman's actions created and prolonged debilitating addictions; distributed countless drugs to be sold on the street; and took the lives of numerous individuals who died just days after visiting him," they said. The 64-year-old Volkman fired his attorneys earlier this month and said he acted at all times as a doctor, not a drug dealer.

"The typical drug dealer does not care how much drugs a client buys, how often he buys, or what he does with his drugs," Volkman said in a 28-page handwritten court filing Monday, maintaining that he did all those things and more for his patients.

0-12, 2012  
N A L  
ABUSE  
MIT



# Prescriptions like candy

The story of a Duarte doctor makes it clear a lot can go wrong between the handcuffs and the prison time.

**SANDY BANKS**

We're getting tough on drug dealers in Los Angeles these days, sweeping crack sellers off skid row streets, shutting down marijuana dispensaries, prosecuting doctors who peddle prescriptions like candy to patient addicts.



But the story of Dr. Daniel Healy makes it clear that a lot can go wrong between the handcuffs and the prison time.

Healy, according to prosecutors, is a most prolific drug dealer. In 2008 alone, he illegally distributed enough prescription drugs to constitute the federal government's equivalent of more than 50 kilos of cocaine or 37,000 pounds of marijuana.

The Duarte physician ordered more Vicodin than any doctor in the nation — 1 million pills in 2008. That's 10 times the stockpile of an average pharmacy; more than his local CVS, Wal-Mart, Target and City of Hope pharmacies combined.

According to federal legal briefs, Healy made so many over-the-counter sales from his "Kind Care" medical clinic, the office had its own money-counting machine and Healy pocketed "\$3,000 to \$6,000 a day."

On the day he was arrested, police pulled over a

ghetto street dealer with a wad of cash and pocketful of crack cocaine.

That guy would have received a mandatory five years in prison for selling as little as five grams of crack.

Healy's lawyer argued that a lengthy term in jail was "not necessary to deter Dr. Healy from engaging in future criminal conduct, or to protect the public from his future criminal acts."

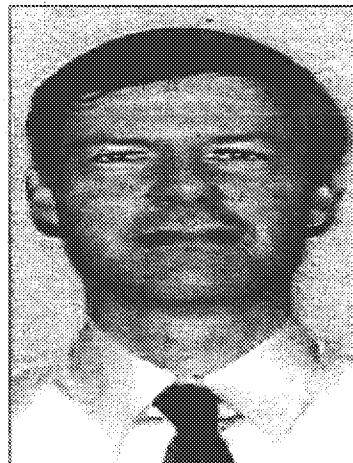
Attorney Roger Rosen called his client a "gifted healer who provided quality medical care" to a working-class community with few options for affordable care.

The prosecutors, drawing an investigation by Monrovia police and the Drug Enforcement Administration, painted a far different picture.

Healy operated in two ways: "writing prescriptions for his customers to fill, or more commonly by selling [pills] directly from his clinic to any customers who could pay." Those customers often dealt the medication on the streets and came quickly back for more, legal papers said.

Healy's dealings became so blatant, local pharmacists refused to fill prescriptions he wrote for his patients' prescriptions because they came in so often, involved large quantities of controlled substances and patients tended to pay in cash for the drugs.

Investigators matching his inventory against his pharmacy orders and pre-



**DOCTOR:** Prosecutors say Daniel J. Healy is a prolific drug dealer.

scription records couldn't account for 890,296 of the pills he ordered the year before he was arrested, court papers said.

Healy's Kind Care clinic was little more than a "narcotics mill" that netted him almost \$700,000 in one year: "a cash-and-carry narcotics store under the guise of providing legitimate medical treatment."

The prosecutor in the case stopped short of saying he's disappointed when I interviewed him Monday.

"Forty-eight months is a significant sentence, by any measure," said Assistant U.S. Atty. David Herzog.

The felony conviction

means Healy will lose his license. "The end result is that this defendant is no longer able to distribute narcotics into the community and never will again."

But 48 months is considerably less than the 210-month minimum term the probation report recommended. It's less, even, than the 57 months Healy's lawyer suggested would be fair.

That's a blow to DEA efforts to crack down on abuse of prescription drugs, which is rising among teens and young adults.


Nearly 7 million Americans are abusing pharmaceutical drugs — up from 3.8 million 10 years ago, and more than the number addicted to cocaine, heroin and hallucinogens. Opioid painkillers — the kind Healy dispensed — cause more overdose deaths than cocaine and heroin combined.

Blatant drug-dealing by doctors is rare. More common is doctor-shopping by patients, thefts from pharmacies, trading meds by addicts and illicit street sales by drug dealers.

That's why Healy's sentence is so disappointing.

Here's a chance to send a message to "well-meaning" doctors like Healy who might be tempted by easy money and to suffering patients who might not realize that the mild-mannered guy with the stethoscope might have more than their well-being in mind.

sandy.banks@latimes.com

The background of the slide features a large, faint, and slightly blurred image of interlocking gears. The gears are arranged in a circular pattern, with several visible teeth and internal structures, suggesting a mechanical or systemic theme. The overall tone is dark and industrial.

# Burden on the health care delivery system



# What is the Societal Damage?



# 2009 Current Users 2010

## ANY ILLICIT DRUG:

21.8 million  
(8.7% of population)

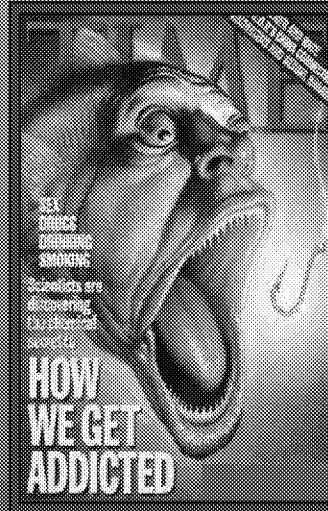
MARIJUANA: 16.7 million

PSYCHOTHERAPEUTIC  
DRUGS: 7 million

COCAINE: 1.6 million

Hallucinogens: 1.3 million

METHAMPHETAMINE: 502,000



Source: 2009 & 2010 NSDUH

## ANY ILLICIT DRUG:

22.6 million  
(8.9% of population)

MARIJUANA: 17.4 million

PSYCHOTHERAPEUTIC  
DRUGS: 7 million

COCAINE: 1.5 million

Hallucinogens: 1.2 million

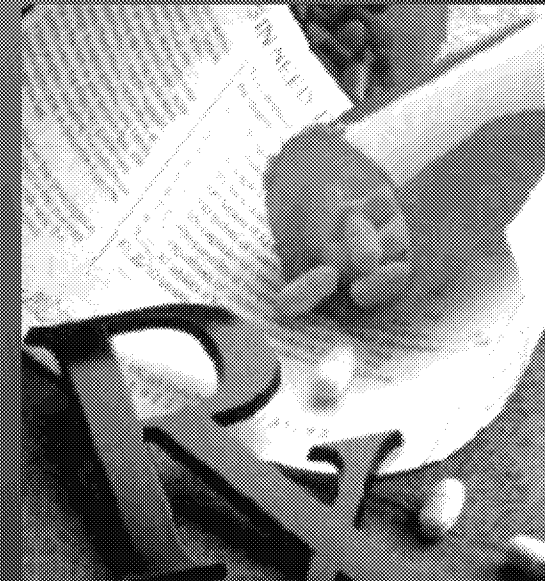
METHAMPHETAMINE: 353,000

# Prescription Drug Abuse

More Americans abuse prescription drugs than the number of:

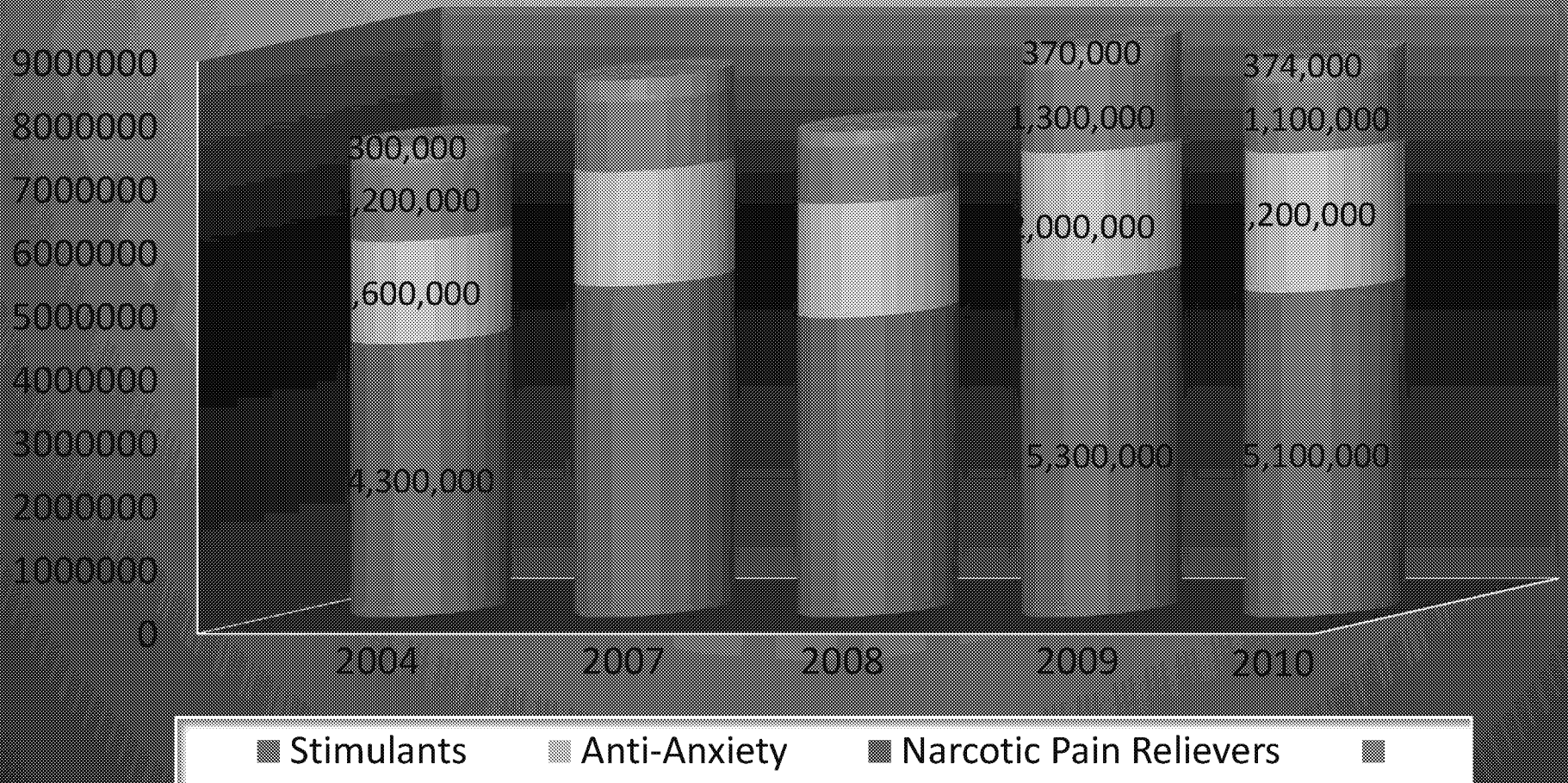
Cocaine, Hallucinogen, Heroin, and Inhalant abusers

**COMBINED!!!**





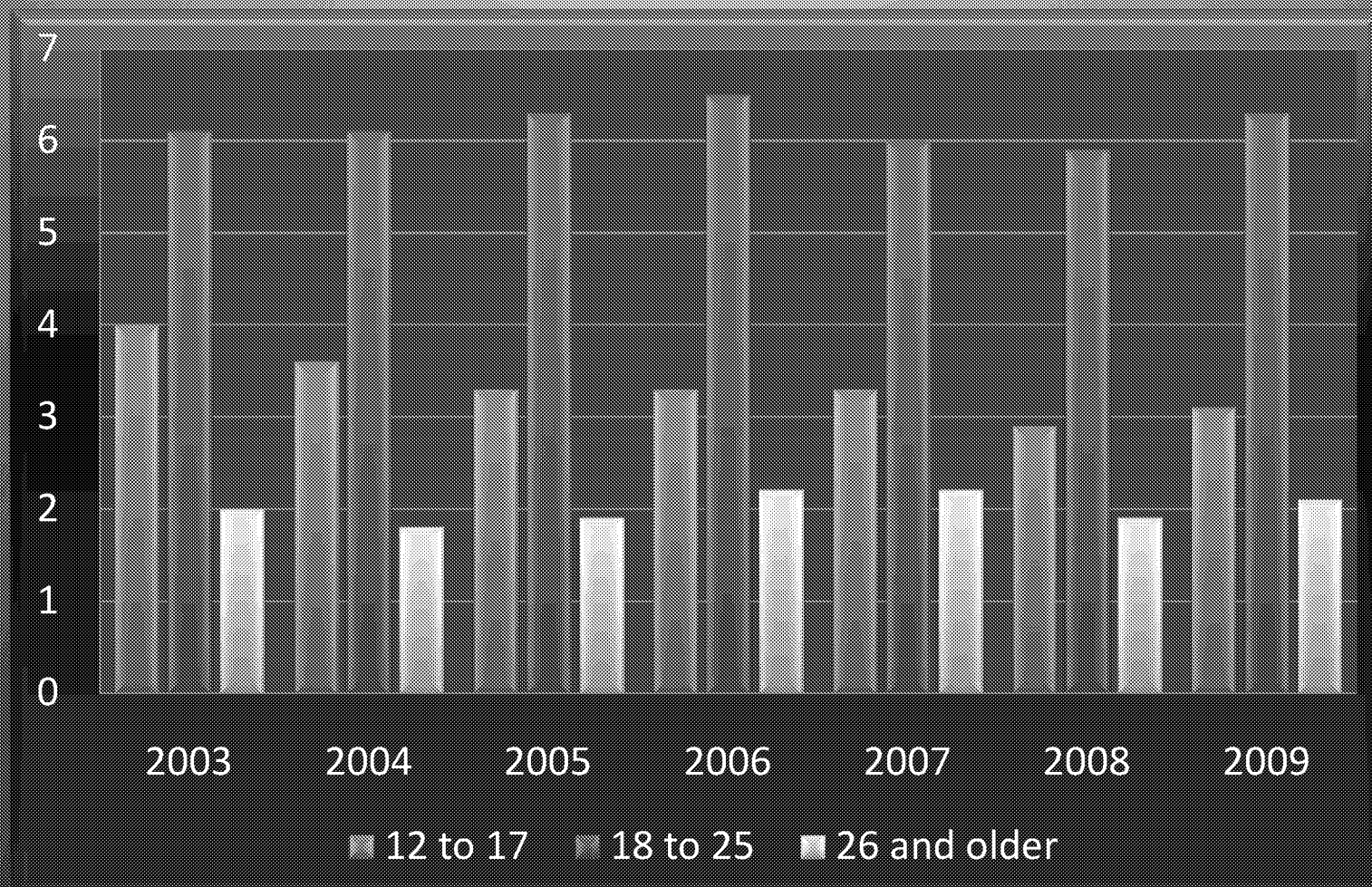
## *Scope and Extent of Problem*



Source: 2004, 2007, 2008, 2009, 2010 National Survey on Drug Use and Health



# *Percentage of Past Month Nonmedical Use of Psychotherapeutics by Age, 2003-2009*



Source: National Survey on Drug Use and Health

# Violence





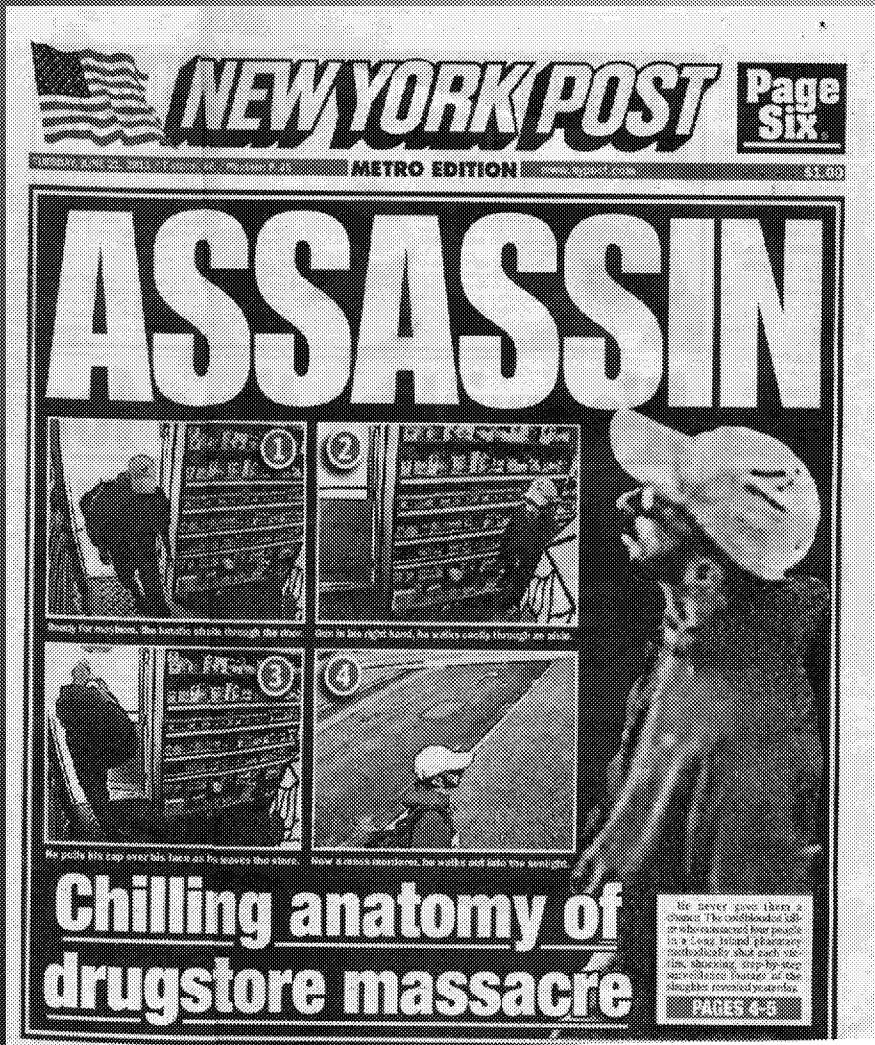
2011

Office of Diversion Control

32



# Violence Related to Controlled Substance Pharmaceuticals





23 of 34



Nassau police respond to the scene of a

Nassau police respond to the scene of a shooting Saturday at Charlie's Family Pharmacy, 3931 Merrick Rd., in Seaford. (Dec. 31, 2011) Photo Credit Kevin P. Coughlin



Long Island

## Robbery suspect, federal agent killed in Seaford

A robbery suspect and a federal agent who had dropped by to pick up a prescription for his ailing father both died of gunshot wounds Dec. 31, 2011, after police struggled with the suspect in the doorway of a Seaford pharmacy.

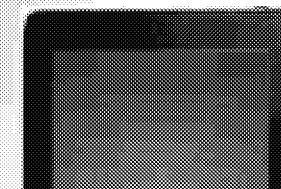
Be the first to rate: ★★★★★ [Click to rate](#)

### Related



Nassau  
Cops: Fatal shooting at  
Seaford drugstore

# Newsday



GO  
MOBILE!  
Get

## Westchase teachers learn a lesson: Say 'no' to mints in pill bottles



One of the mint-filled pill bottles distributed to some fourth graders at Westchase Elementary.

By JOSÉ PATIÑO GIRONA | The Tampa Tribune

Published: February 8, 2010

What two fourth-grade teachers at Westchase Elementary School apparently thought was a creative way to calm students about to take the FCAT made at least one caregiver fear the teachers were sending a different message — that taking drugs while under stress is OK.

Sandy Young walked into her grandson's fourth-grade classroom last Thursday and saw pill bottles on each students' desk. Her mind raced with questions and thoughts of disbelief.

Young said she immediately questioned Westchase Elementary fourth-grade teacher Beth Watson about the pill bottles, which were filled with pieces of small mint candy.

"She said it was nothing but some mints; it was just something special for the kids, for the FCAT to mellow them out," Young said.

Young said she was shocked and speechless and walked out of the room when Watson started the students on a math assignment.

Young said the pill bottles go against the lessons of teaching children to say no to drugs.

"We turn around and we have our teachers giving them drugs," said Young, 60, of Tampa. "I don't care if it's mints or not. ... If it's in a prescription bottle, it's a drug."

Young said the bottle reads in part, "Watson's Whiz Kid Pharmacy. Take 1 tablet by mouth EVERY 5 MINUTES to cure FCAT jitters. Repeated use may cause craft to spontaneously ooze from pores. No refills. Ms. (Deborah) Falcon's authorization required."

The school received one complaint since pill bottles were distributed on Thursday, said Linda Cobbe, a school district spokeswoman. It's believed only two fourth-grade teachers at the school distributed the pill bottles.

The principal met with the students on Monday to confirm the pill bottles contained mints that were safe to eat. The students were asked to dump the mints in a separate container and the pill bottles were thrown away, Cobbe said.

She said the bottle idea was tied to the children's book the students recently read, "George's Marvelous Medicine," about a boy who concocts potions to try to change the disposition of his cranky grandmother.

The teachers were just trying to use a creative way to get across to the students not to be stressed with the FCAT writing examination that will be administered to fourth-, eighth- and 10th-graders beginning today, Cobbe said.

"Elementary teachers do creative things to make learning fun," Cobbe said.

The teachers won't be disciplined, and it wasn't their intention to promote drug use, Cobbe said.

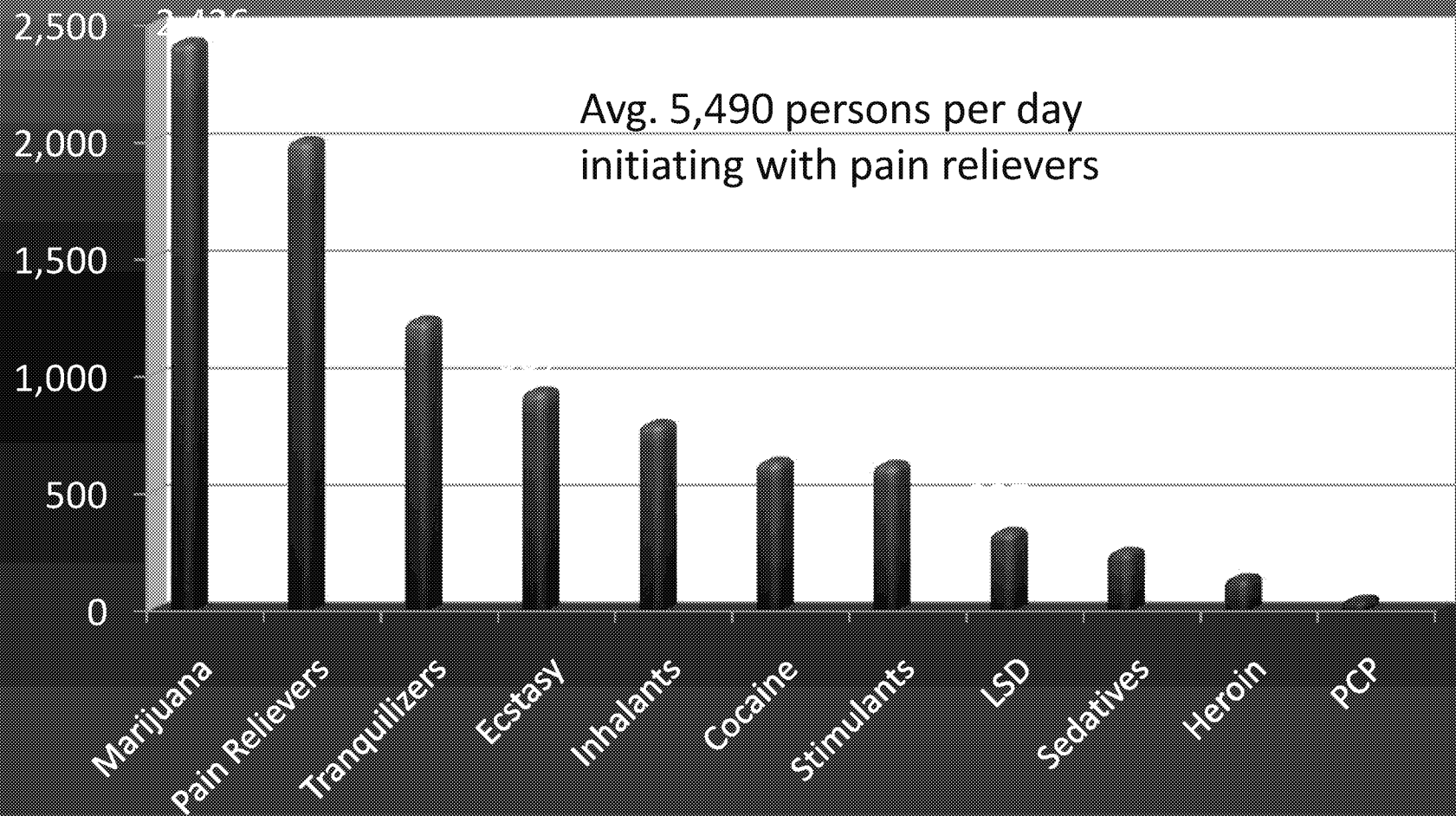
"I know that is not the intent of the teachers," Cobbe said. "That is not the outcome they would wish for."

Young said her grandson has been at Westchase Elementary for a year, and she hasn't had any complaints. But this experience has soured her. It concerns her that now someone might hand her grandson a pill bottle with drugs and he might think it's OK to consume its contents.

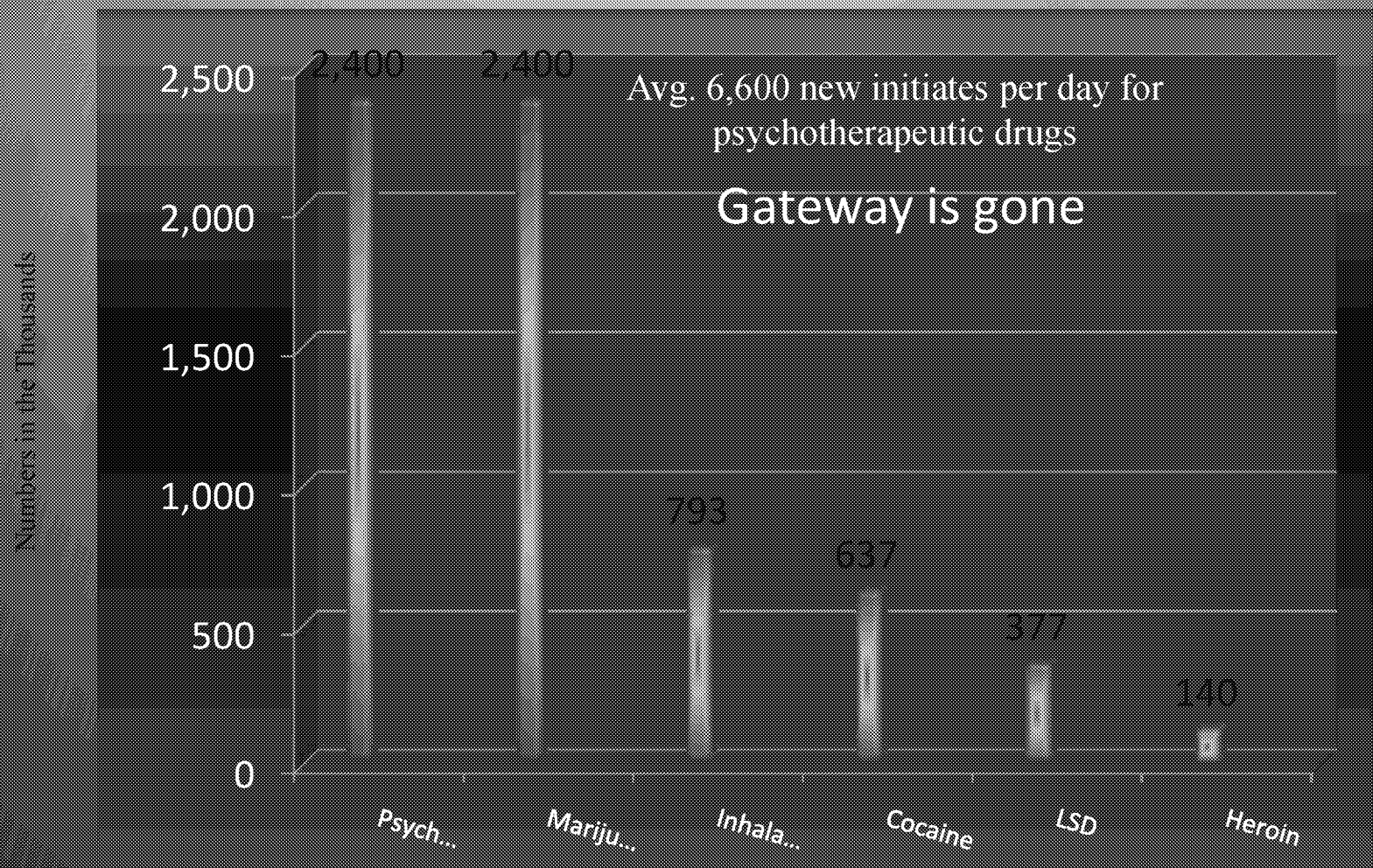
"We as parents and grandparents have to drill it into them that this is unacceptable and hope and pray that they don't accept drugs from someone else," Young said.



## *Past Year Initiates for Specific Drugs Persons Aged 12 or Older 2010*



## *New Initiates 2010 - 12 years and older*



Source: 2010 NSDUH

Psychotherapeutics Include: Pain Relievers, Tranquilizers, Stimulants, and Sedatives



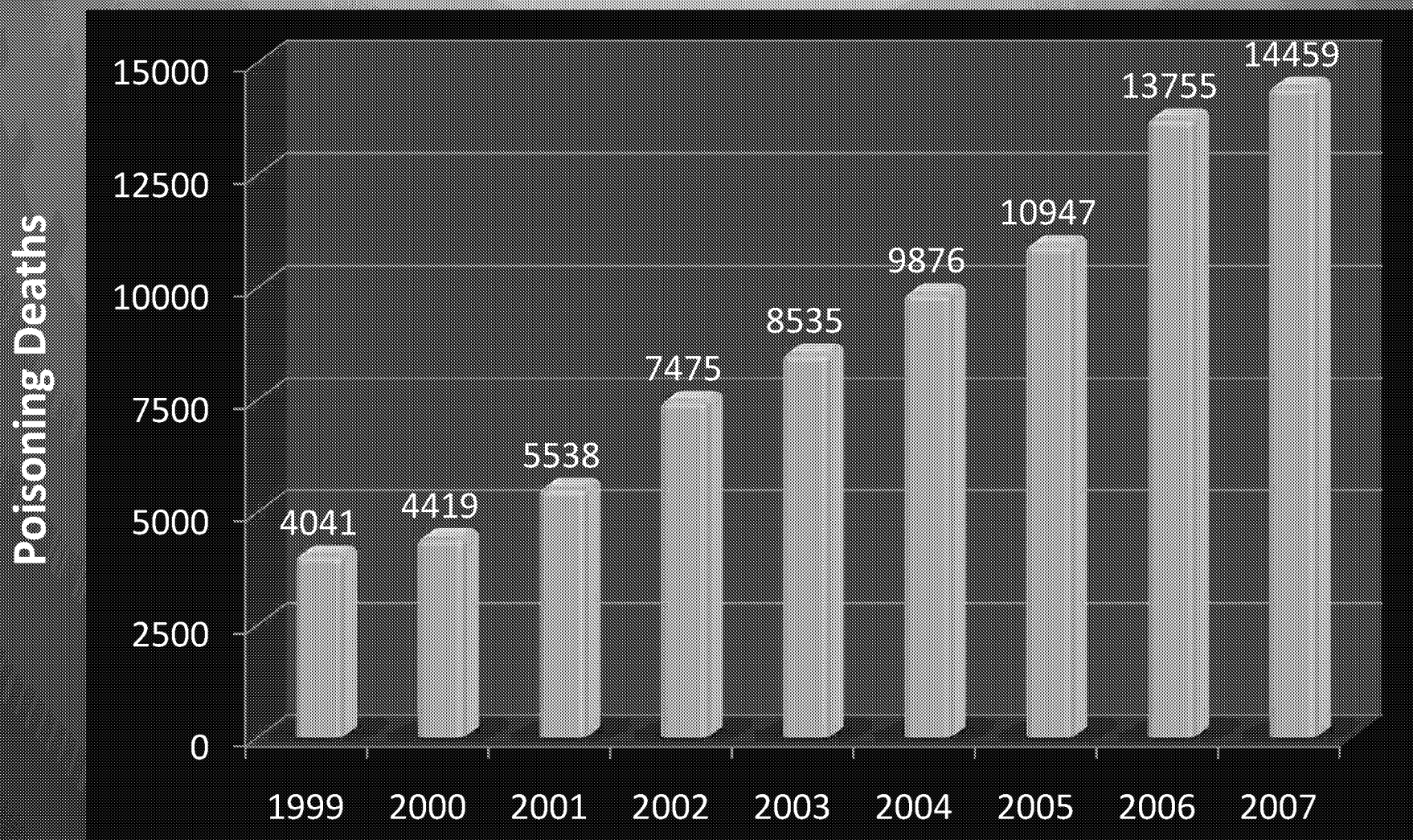
# *Emergency Room Data 2004-2009*

- Increase of 98.4%: ER visits attributable to pharmaceuticals alone  
(i.e., with no other type of drug or alcohol) (627,291 to 1,244,679)
  - No Significant Change: ER visits attributable to cocaine, heroin, marijuana, or methamphetamine
- Rx Drugs most frequently implicated:
  - **Opiates/Opioids pain relievers**
    - Oxycodone products 242.2% increase
    - Hydrocodone products 124.5% increase
    - Fentanyl products 117.5% increase
  - **Insomnia or Anti-Anxiety medications**
    - Zolpidem 154.9% increase
    - Alprazolam 148.3% increase
    - Clonazepam 114.8% increase
  - **Carisoprodol 100.6% increase**
  - For patients aged 20 and younger misuse/abuse of pharmaceuticals increased 45.4%
  - For patients aged 20 and older the increase was 111%

SOURCE: The DAWN Report, *Highlights of the 2009 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits*, December 28, 2010



# Poisoning Deaths: Opioid Analgesics

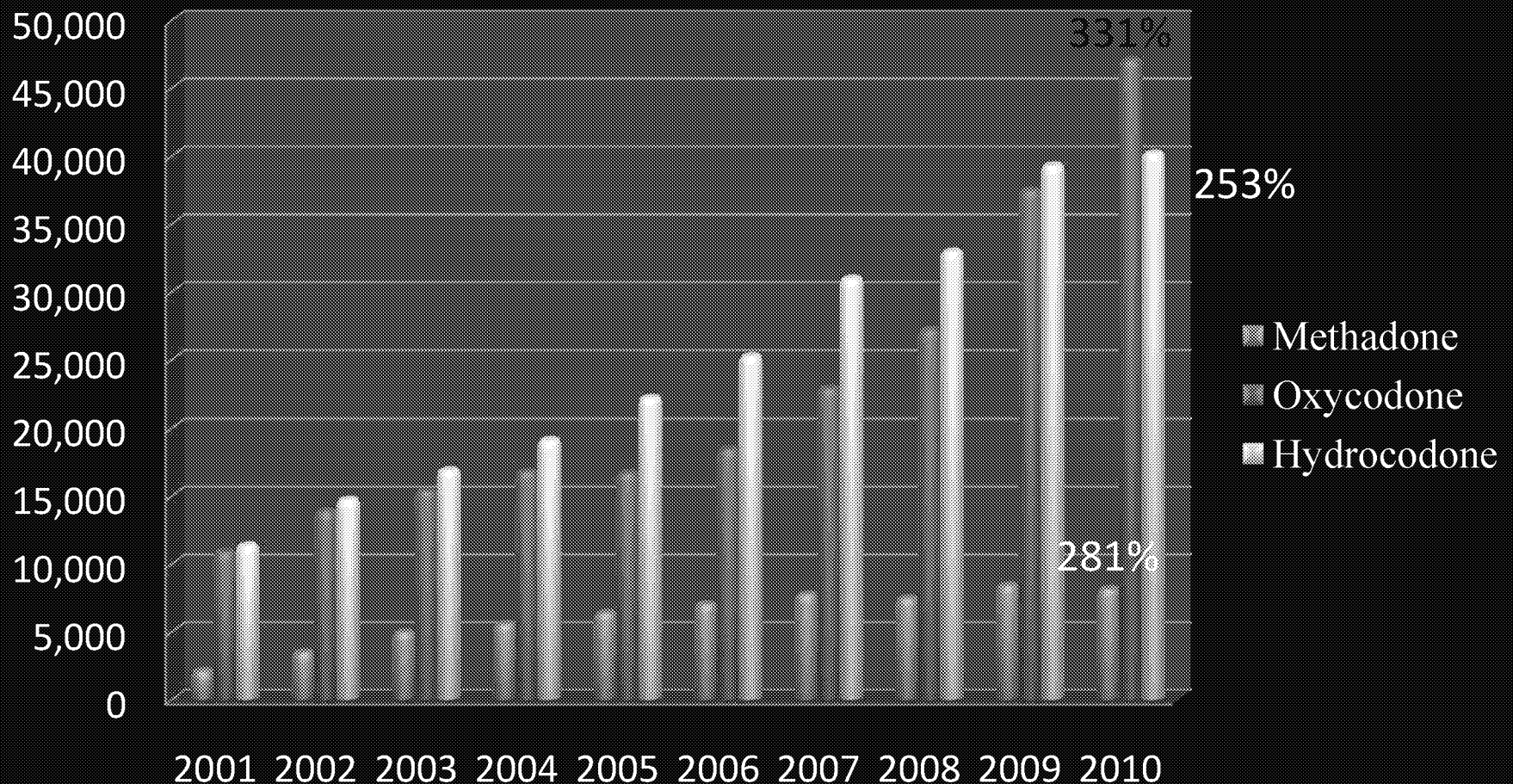


Source: CDC/NCHS, National Vital Statistics System

# *Number of Forensic Cases*

## *2001-2010*

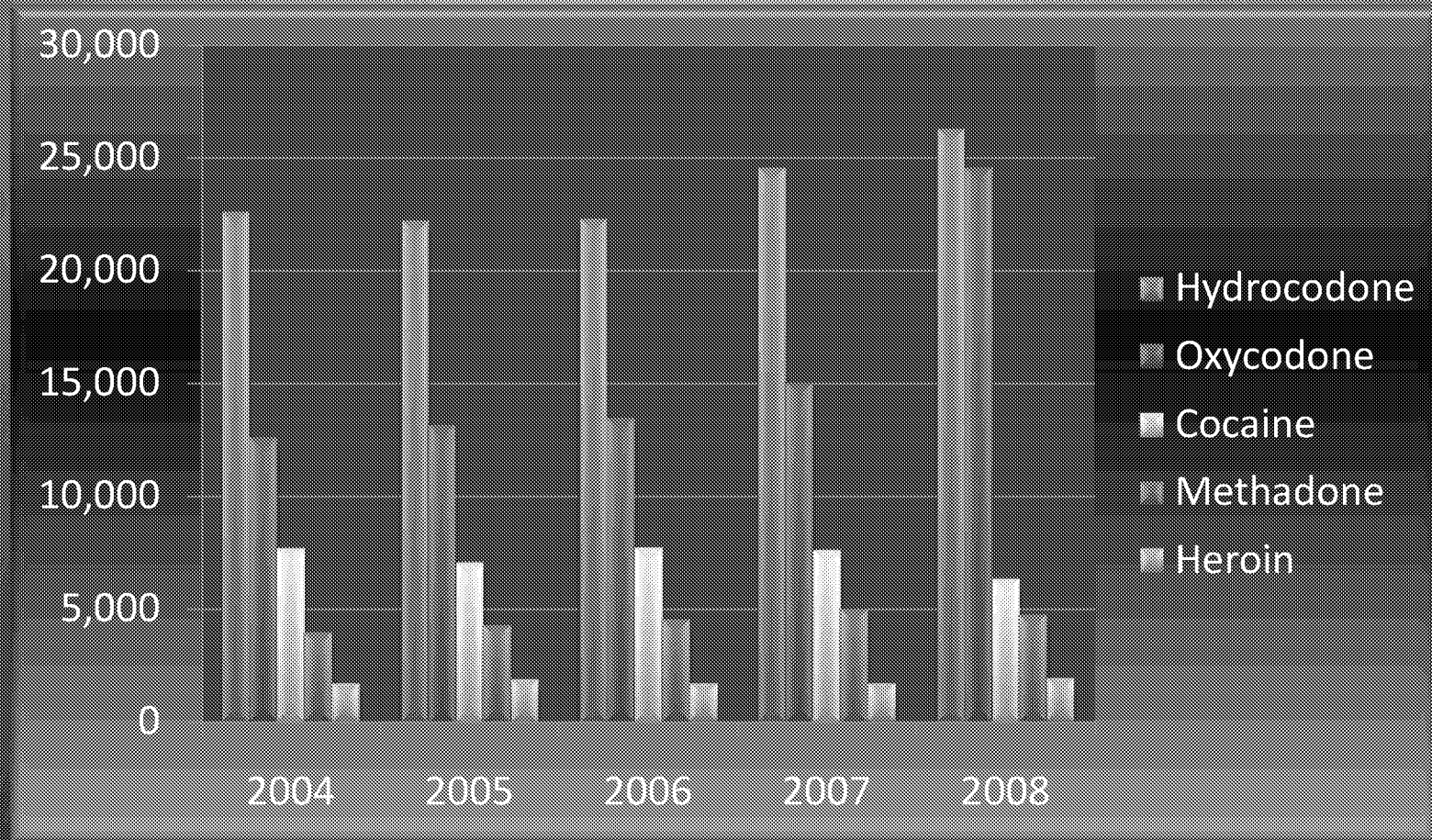
NFLIS  
Estimated U.S. Law Enforcement Encounters





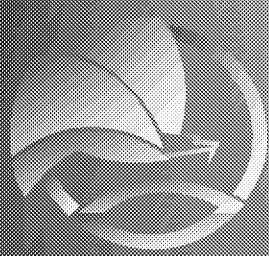
*National Poison Data Center*  
*Number of U.S. Poison Exposure Case Mentions*  
*2004 - 2008*

Number of U.S. Poison Case Mentions



Source: American Association of Poison Control Centers (AAPCC) Annual Reports, 2004-2008





# *Statistical Perspective*

**The U.S. Population Grows at a Rate of  
Less Than 1% Per Year!**

Source: U.S. Census Bureau

# Sources of Information and Risks

% Learned a lot about risks of drugs from...	1998	2004	2005	2007	2008	2009
School	41	42	38	37	44	39*
Parents	26	28	28	29	35	31
TV Commercials	17	36	26	31	31	26*
The Internet	11	23	22	25	29	29
Websites like YouTube	NA	NA	NA	NA	14	17*
* = Significant at the .05 level vs 2008						

Source: Partnership for Drug Free America, March 2, 2010

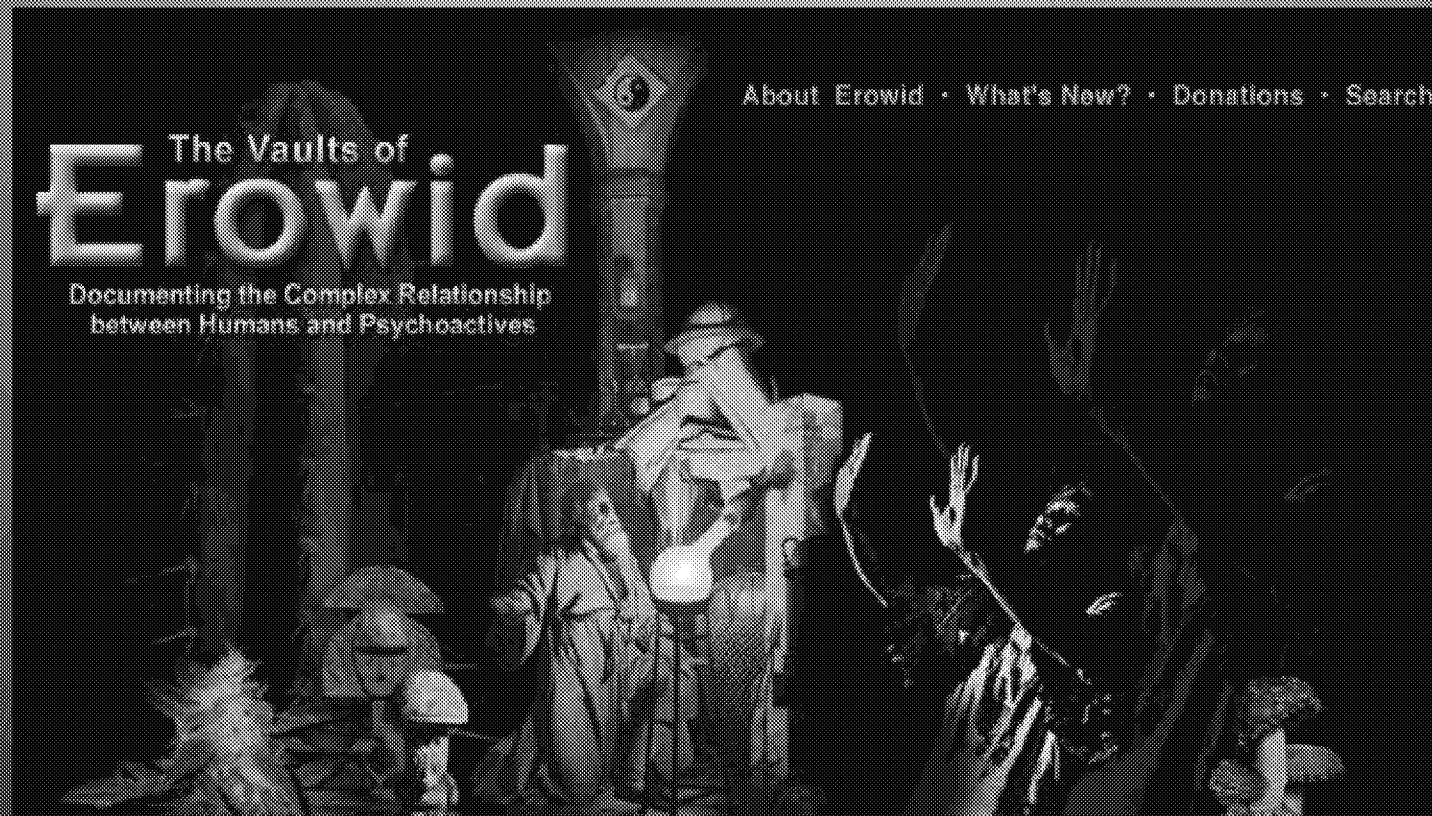


## *Teens and Their Attitudes*

<b>% Agree strongly/somewhat</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>
<b>Prescription drugs are available everywhere</b>	<b>42</b>	<b>55</b>	<b>38</b>
Its easy to get prescription drugs from parent's medicine cabinets	56	63	47
<b>Most teens get prescription drugs from their own family's medicine cabinets</b>	<b>59</b>	<b>62</b>	<b>51</b>
Most teens get prescription drugs from their friends	53	62	49



# Where do kids get their information from?



# *Parents and Their Attitudes*

Parents are still not discussing the risks of abusing prescription and over-the-counter medicines

Percent	2008	2009	2010
Beer/alcohol	79	79	81
Marijuana	79	79	77
Cocaine/crack	36	35	30
Prescription pain reliever w/o doctor's Rx	20	20	23
Any prescription drug used w/o doctor's Rx	21	20	22
Heroin	23	23	21
Ecstasy	21	20	21
Methamphetamine	23	21	21
Non-prescription cold/cough medicine to get high	15	14	15

# Who are the Victims of Prescription Drug Abuse

- The drug abuser
- Children
- Parents / Family members
- Society / Taxpayer
  - Loss of productivity
  - Cost of uncompensated medical costs
  - Cost of social services
  - Costs for treatment
  - Cost to judicial system

— Orlando, FL • April 10-12, 2012 —  
NATIONAL  
RX DRUG ABUSE  
SUMMIT  
National Prescription Drug Abuse Summit.org



# Economic Impact – The Cascading Effect

2006 estimated cost in the United States from  
nonmedical use of prescription opioids

**\$53.4 BILLION**

- \$42 billion – Lost productivity
- \$8.2 billion – Criminal Justice costs
- \$2.2 billion – Treatment costs
- \$944 million – Medical complications

Five drugs –

OxyContin, oxycodone, hydrocodone, propoxyphene, and methadone accounted for two-thirds of the economic burden

Source: Clinical Journal of Pain, December 2010, University of Washington, Hansen RN; Oster, G; Edelberg, J; Woody, GE; and Sullivan, SD

# We will not arrest our way out of this problem!!!!

- Enforcement is just as important as....
- Prevention/Education
- Treatment





# ONDCP Strategy

## “Epidemic: Responding To America’s Prescription Drug Abuse Crisis” (Released in April 2011)

### Highlights:

- Education
  - Healthcare Provider Education
  - Parent, Youth, and Patient Education
- Tracking and Monitoring
  - Work with states to establish effective PDMPs
  - Support NASPER
  - Explore reimbursements to prescribers who check PDMPs before writing a prescription





# ONDCP Strategy con't

- Proper Medicine Disposal
- Enforcement
  - Assist states address doctor shopping and pill mills
  - Increase HIDTA intelligence-gathering and investigation of prescription drug trafficking
  - Expand the use of PDMPs to identify criminal prescribers and clinics
- Prescription Drug Abuse Plan Goals
  - 15% reduction in non-medical use of prescription-type psychotherapeutic drugs;
  - Write and disseminate a Model Pain Clinic Regulation Law within 12 months;
  - Implement REMS for long-acting and extended release opioids within 12 months

# Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!



# The Medicine Cabinet and the Problem of Pharmaceutical Controlled Substance Disposal

# The Problem – Easy Access



— Orlando, FL • April 10-12, 2012 —  
**NATIONAL  
RX DRUG ABUSE  
SUMMIT**  
National Rx Drug Abuse Summit.org

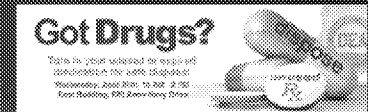


# CSA Definitions

- An “ultimate user” is a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.
- To distribute means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.

# Ultimate User Disposal of Medicines

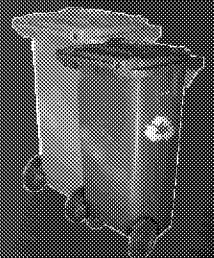
**National Take-Back Events:** Take-back events are a good way to remove expired, unwanted, or unused medicines from the home.



**Law Enforcement Collection Bins:** Collection bins installed by our Law Enforcement Partners are a good way to remove expired, unwanted, or unused medicines from the home.



**Disposal in Household Trash:** Mix medicines (do not crush tablets or capsules) with substances such as kitty litter or used coffee grounds and place the mixture in a container such as a sealed plastic bag and throw the container in your household trash.



**Disposal by Flushing:** Some medicines have specific disposal instructions that indicate they should be flushed down the sink or toilet when they are no longer needed.





# Law Enforcement

- Law enforcement officers, acting to enforce laws regarding the abandonment of controlled substances, may receive controlled substances from ultimate users.
- Law enforcement must safeguard the controlled substances and ensure that they are destroyed properly.
- Law enforcement must be present during the destruction of the controlled substances.

# So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules

— Orlando, FL • April 10-12, 2012 —  
NATIONAL  
RX DRUG ABUSE  
SUMMIT  
National Rx Drug Abuse Summit, Inc.



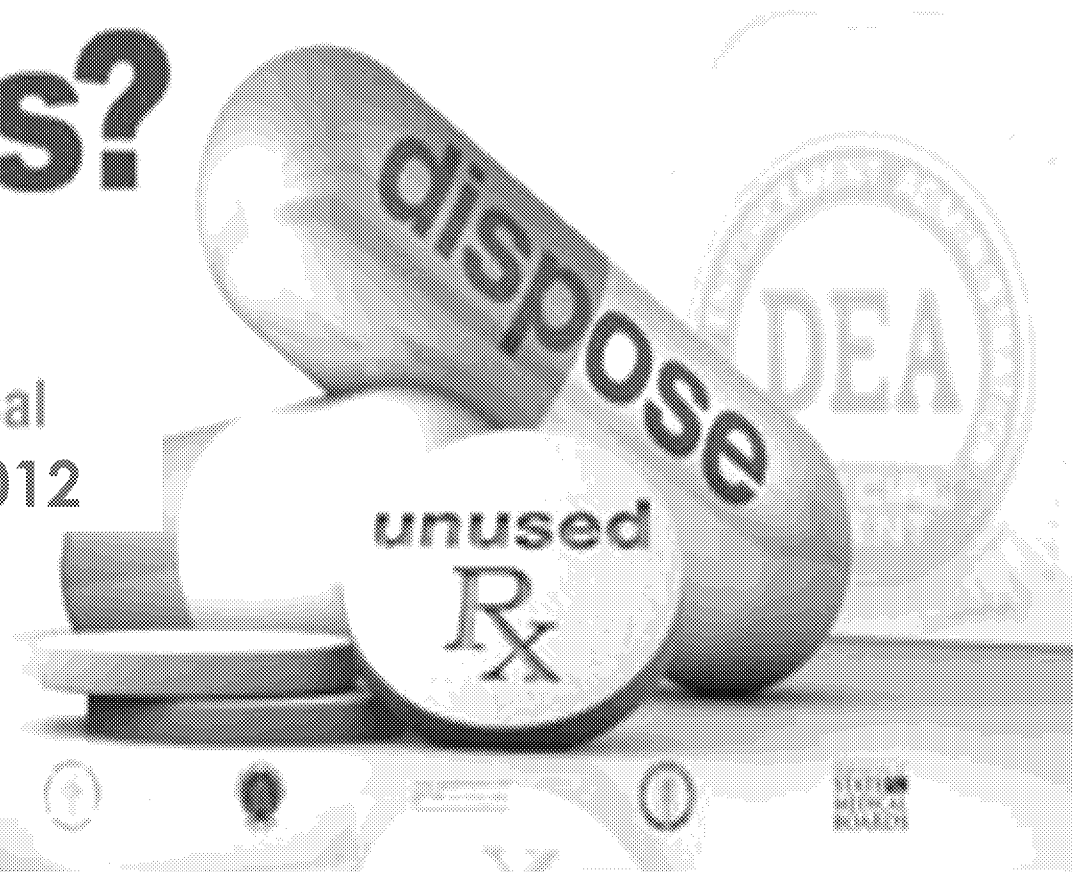
# National Take Back Initiative

## September 29, 2012

# Got Drugs?

Turn in your  
unused or expired  
medication for safe disposal  
Saturday, Sept 29, 2012

Click here  
for a collection  
site near you.

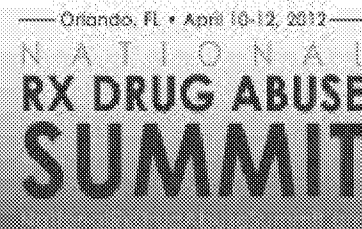


# SUMMIT

National Take Back Initiative

# Nationwide Take-back Initiative

- On September 30, 2010, 122 tons of prescription drugs collected
- On April 30, 2011, 188 tons of prescription drugs collected
- On October 29, 2011, 189 tons of prescription drugs collected
- On April 28, 2012, approximately 272 tons of prescription drugs collected (est.)





# Secure and Responsible Drug Disposal Act of 2010

- Enacted in October 2010 (Pub. L. 111-273, codified at 21 U.S.C. 822(g) and 823(b)(3))
- Act allows an ultimate user to “deliver” a controlled substance “to another person for the purpose of disposal” in accordance with regulations issued by DEA
- If the ultimate user dies while in lawful possession of the controlled substance, then any person lawfully entitled to dispose of the decedent’s property may deliver the controlled substance to another person for the purpose of disposal.
- DEA may also, by regulation, authorize long term care facilities (LTCFs) to dispose of controlled substances on behalf of ultimate users who reside or have resided at the LTCE.
- DEA is working to promulgate regulations to implement this Act. DEA must consider:
  - Public health and safety
  - Ease and cost of program implementation
  - Participation by various communities
  - Diversion Control
- Participation is voluntary. DEA may not require any person to establish or operate a delivery or disposal program.

# ONDCP Guidelines

- ONDCP guidelines for the disposal of ultimate user medications, including dispensed controlled substances (2/20/07).
- Advise public to flush medications only if the prescription label or accompanying patient information specifically states to do so.
- ONDCP recommends a minimal deactivation procedure, and disposal in common household trash.



# PROZAC (?) FISH





# MEDICINES RECOMMENDED FOR DISPOSAL BY FLUSHING

This list from FDA tells you what expired, unwanted, or unused medicines you should flush down the sink or toilet to help prevent danger to people and pets in the home. Flushing these medicines will get rid of them right away and help keep your family and pets safe.

FDA continually evaluates medicines for safety risks and will update the list as needed.

Medicine	Active Ingredient
Abstral, tablets (sublingual)	Fentanyl
Actiq, oral transmucosal lozenge *	Fentanyl Citrate
Avinza, capsules (extended release)	Morphine Sulfate
Daytrana, transdermal patch system	Methylphenidate
Demerol, tablets *	Meperidine Hydrochloride
Demerol, oral solution *	Meperidine Hydrochloride
Diastat/Diastat Acu/Dial, rectal gel	Diazepam
Dilaudid, tablets *	Hydromorphone Hydrochloride
Dilaudid, oral liquid *	Hydromorphone Hydrochloride
Dolophine Hydrochloride, tablets *	Methadone Hydrochloride
Duragesic, patch (extended release) *	Fentanyl
Embeda, capsules (extended release)	Morphine Sulfate, Naltrexone Hydrochloride
Exalgo, tablets (extended release)	Hydromorphone Hydrochloride
Fentora, tablets (buccal)	Fentanyl Citrate
Kadian, capsules (extended release)	Morphine Sulfate
Methadone Hydrochloride, oral solution *	Methadone Hydrochloride
Methadose, tablets *	Methadone Hydrochloride
Morphine Sulfate, tablets (immediate release) *	Morphine Sulfate
Morphine Sulfate, oral solution *	Morphine Sulfate
M-S Contin, tablets (extended release) *	Morphine Sulfate
Nucynta ER, tablets (extended release)	Tapentadol
Onsolis, soluble film (buccal)	Fentanyl Citrate
Opana, tablets (immediate release)	Oxymorphone Hydrochloride
Opana ER, tablets (extended release)	Oxymorphone Hydrochloride
Oramorph SR, tablets (sustained release)	Morphine Sulfate
Oxecta, tablets (immediate release)	Oxycodone Hydrochloride
Oxycodone Hydrochloride, capsules	Oxycodone Hydrochloride
Oxycodone Hydrochloride, oral solution	Oxycodone Hydrochloride
Oxycontin, tablets (extended release) *	Oxycodone Hydrochloride
Percocet, tablets *	Acetaminophen, Oxycodone Hydrochloride
Percodan, tablets *	Aspirin, Oxycodone Hydrochloride
Xyrem, oral solution	Sodium Oxylate

\*These medicines have generic versions available or are only available in generic formulations.

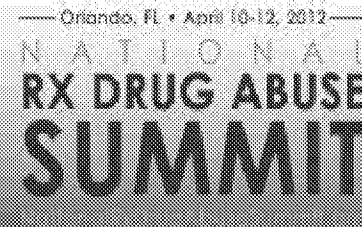
List revised: January 2012

Consumers are advised to check their local laws and ordinances to make sure medicines can legally be disposed of with their household trash.

For specific drug product labeling information, go to DailyMed or Drugs@FDA.

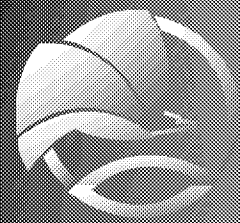
# Other Trends Related to the Medicine Cabinet

- Real estate
- Trip to relatives/friends house
- Easy access at home





# Controlled and Legend Pharmaceuticals

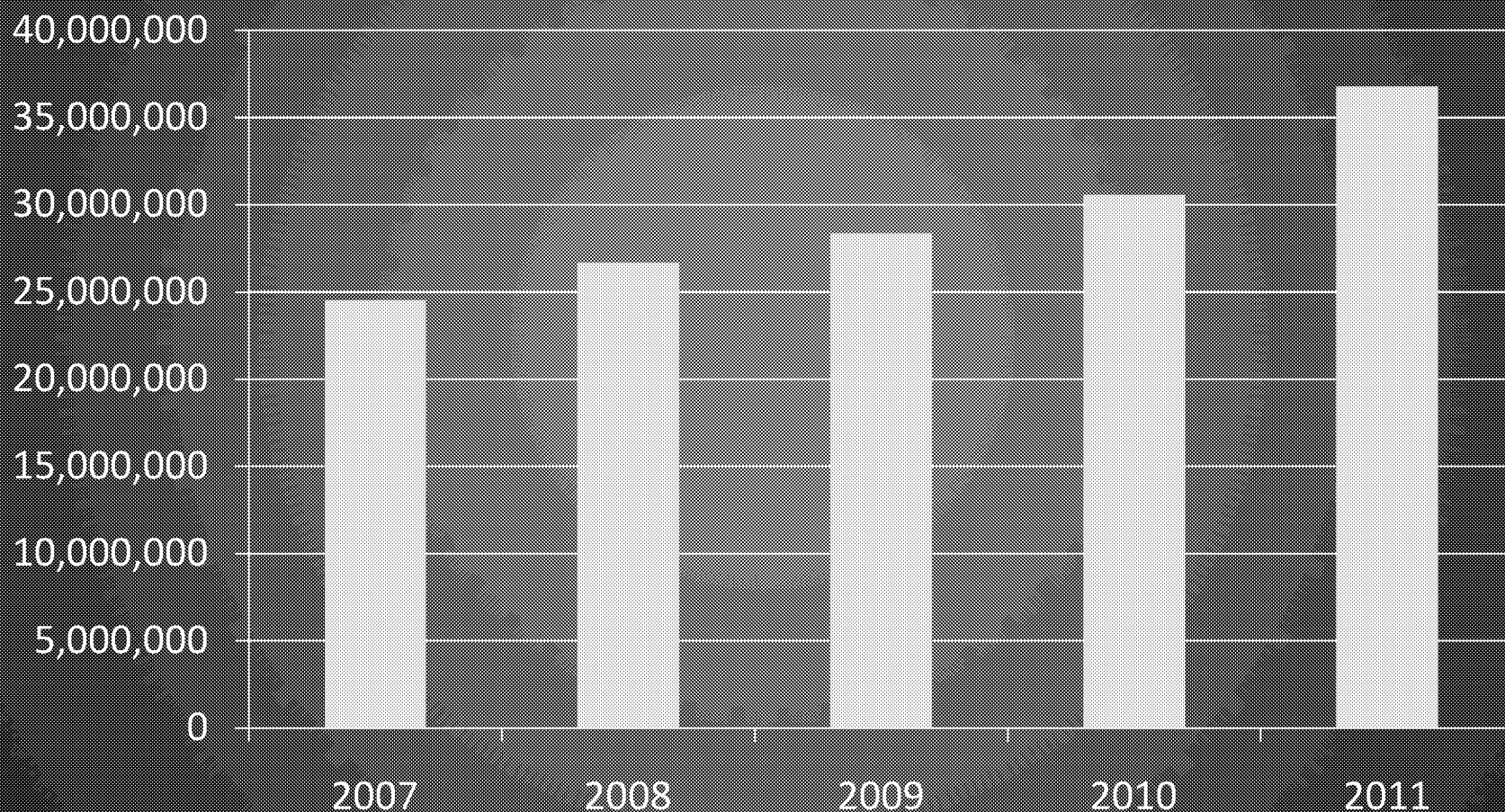


# Non-Controlled Substances

- Analgesic:
  - Tramadol (Ultram®, Ultracet®)
- Muscle Relaxant:
  - Cyclobenzaprine (Flexeril®)



# Tramadol Prescriptions



Source: IMS Health National Prescription Audit Plus downloaded 6/5/2012



# NFLIS Data

Reporting period:

January 2011 through June 2011

Tramadol

720 reports

1.09%

# Most commonly prescribed prescription medicine?

## Hydrocodone/acetaminophen



# Top Five Prescription Drugs Sold in the U.S. (2006-2010)

Source: IMS Health

140,000,000

(By Number of Prescriptions Sold)

120,000,000

100,000,000

80,000,000

60,000,000

40,000,000

20,000,000

0

2006

2007

2008

2009

2010

112,400,000

119,200,000

124,100,000

128,200,000

131,200,000

■ Hydrocodone/Apap

■ Lipitor

■ Amoxicillin

■ Lisinopril

■ Simvastatin

■ Levothyroxine

■ Azithromycin



# Top 50 Generic Drugs by Total Prescriptions 2010

Rank	Drug	Total Rxs	Change from Previous Year	Rank	Drug	Total Rxs	Change from Previous Year
1	Hydrocodone/APAP	122,806,850	2.10%	26	Lorazepam	23,428,627	3.70%
2	Lisinopril	76,901,813	4.30%	27	Warfarin	23,388,338	1.50%
3	Simvastatin	76,771,821	4.90%	28	Clonazepam	23,085,065	4.00%
4	Levothyroxine	68,222,152	8.20%	29	Fluticasone nasal	22,447,832	19.70%
5	Amoxicillin	51,083,822	-0.60%	30	Cyclobenzaprine	22,240,071	7.30%
6	Amlodipine besylate	50,186,652	11.70%	31	Cephalexin	21,943,482	2.70%
7	Azithromycin	48,756,188	-2.10%	32	Trimethoprim/sulfa	21,345,723	4.50%
8	Alprazolam	46,201,182	3.90%	33	Fexofenadine	20,430,430	27.50%
9	Hydrochlorothiazide	45,838,017	-0.80%	34	Amoxicillin/pot clav	20,234,873	1.20%
10	Omeprazole	44,795,175	15.40%	35	Ciprofloxacin HCl	20,063,382	1.80%
11	Metformin	41,932,689	4.70%	36	Pravastatin	20,026,786	17.90%
12	Furosemide oral	36,583,895	-0.10%	37	Trazodone HCl	18,786,495	6.50%
13	Metoprolol tartrate	34,707,807	-0.50%	38	Lovastatin	17,509,951	13.50%
14	Atenolol	33,839,806	-11.00%	39	Triamterene/HCTZ	17,201,037	-7.00%
15	Sertraline	33,409,838	8.90%	40	Carvedilol	16,681,336	8.30%
16	Metoprolol succinate	32,224,000	12.00%	41	Alendronate	16,177,014	-6.90%
17	Zolpidem tartrate	29,719,569	-2.80%	42	Ranitidine HCl	14,699,414	6.60%
18	Oxycodone/APAP	28,705,243	6.80%	43	Meloxicam	14,645,167	2.90%
19	Citalopram HBR	27,993,635	9.40%	44	Diazepam	14,584,147	7.10%
20	Gabapentin	26,865,557	14.00%	45	Naproxen	14,297,759	10.30%
21	Ibuprofen	26,256,548	3.20%	46	Propoxyphene-N/APAP	14,274,354	-18.70%
22	Prednisone oral	25,529,463	-2.70%	47	Fluconazole	13,938,887	4.60%
23	Tramadol	25,527,796	10.30%	48	Methylprednisolone tabs	13,659,852	11.30%
24	Lisinopril/HCTZ	24,538,247	8.00%	49	Doxycycline	13,199,430	1.90%
25	Fluoxetine	24,473,994	6.80%	50	Paroxetine	12,979,366	-14.40%

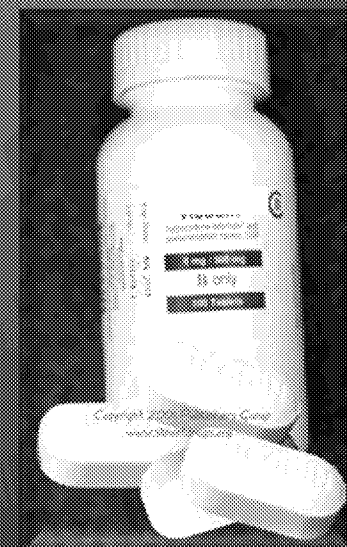
# Top 50 Generic Drugs by Total Prescriptions 2009

Rank	Drug	Total Rxs	Change from Previous Year	Rank	Drug	Total Rxs	Change from Previous Year
1	Hydrocodone/APAP	120,478,000	-0.60%	26	Clonazepam	23,090,000	5.70%
2	Lisinopril	74,544,000	6.80%	27	Lisinopril/HCTZ	22,898,000	12.40%
3	Simvastatin	72,966,000	21.30%	28	Lorazepam	22,436,000	1.80%
4	Levothyroxine	63,710,000	8.70%	29	Cephalexin	21,415,000	-3.00%
5	Amoxicillin	51,430,000	-1.20%	30	Cyclobenzaprine	21,086,000	6.10%
6	Azithromycin	49,902,000	1.30%	31	Amoxicillin/pot. clav.	20,504,000	2.10%
7	Hydrochlorothiazide	46,403,000	-1.40%	32	Trimethoprim/sulfa	20,462,000	40.20%
8	Amlodipine besylate	45,107,000	15.60%	33	Ciprofloxacin HCl	19,673,000	-3.90%
9	Alprazolam	44,467,000	2.00%	34	Fluticasone nasal	18,866,000	16.70%
10	Metformin	42,161,000	5.30%	35	Triamterene w/HCTZ	18,566,000	-8.80%
11	Omeprazole	38,791,000	33.00%	36	Pravastatin	17,827,000	30.90%
12	Atenolol	37,973,000	-7.20%	37	Trazodone HCl	17,740,000	6.20%
13	Furosemide oral	36,774,000	-1.80%	38	Propoxyphene-N/APAP	17,575,000	-13.90%
14	Metoprolol tartrate	36,016,000	21.40%	39	Alendronate	17,458,000	31.00%
15	Sertraline	30,508,000	3.50%	40	Fexofenadine	16,689,000	1.20%
16	Zolpidem tartrate	30,081,000	6.20%	41	Lovastatin	15,498,000	1.30%
17	Metoprolol succinate	27,884,000	-28.30%	42	Carvedilol	15,392,000	20.90%
18	Oxycodone w/APAP	27,238,000	3.80%	43	Paroxetine	15,048,000	-3.30%
19	Prednisone oral	26,291,000	6.20%	44	Meloxicam	14,073,000	17.20%
20	Citalopram HBR	25,856,000	19.90%	45	Diazepam	13,957,000	0.60%
21	Ibuprofen	25,728,000	0.70%	46	Ranitidine HCl	13,817,000	8.70%
22	Fluoxetine	23,417,000	0.60%	47	Fluconazole	13,381,000	3.00%
23	Gabapentin	23,351,000	13.00%	48	Naproxen	13,193,000	0.00%
24	Warfarin	23,287,000	2.00%	49	Doxycycline	13,167,000	5.10%
25	Tramadol	23,282,000	9.40%	50	Amitriptyline	12,904,000	-3.00%



# Hydrocodone, APAP <sup>C-III</sup>

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin<sup>®</sup>, Lortab<sup>®</sup>, Lorcet<sup>®</sup>
- “Cocktail” or “Holy Trinity”
  - Hydrocodone
  - Soma <sup>®</sup> / carisoprodol
  - Alprazolam / Xanax<sup>®</sup>
- Street prices: \$2 to \$10+ per tablet depending on strength & region



# State Ranking - Hydrocodone

## Total Dosage Units Sold to Retail January 1, 2010 – December 31, 2011

2011			2010			2011			2010		
STATE	RANK	TOTAL DOSAGE UNITS	RANK	TOTAL DOSAGE UNITS	% CHANGE 2010 to 2011	STATE	RANK	TOTAL DOSAGE UNITS	RANK	TOTAL DOSAGE UNITS	% CHANGE 2010 to 2011
CA	1	1,070,071,036	1	1,008,085,597	6%	CO	29	96,427,859	29	93,524,023	3%
TX	2	881,240,377	2	825,923,242	6%	MN	30	76,880,520	30	73,153,391	5%
TN	3	439,728,700	3	475,681,320	-8%	IA	31	74,022,276	31	68,748,014	7%
MI	4	436,081,376	5	397,828,308	9%	MA	32	66,153,063	32	64,746,507	2%
FL	5	412,449,314	4	402,021,110	3%	NJ	33	64,979,025	34	61,551,852	5%
OH	6	319,235,352	6	303,268,137	5%	UT	34	64,669,054	33	64,047,210	1%
IL	7	316,944,665	7	288,359,428	9%	MD	35	56,853,556	35	55,061,251	3%
IN	8	294,538,688	9	269,256,309	9%	ID	36	53,514,031	36	49,084,374	8%
NY	9	283,936,955	8	287,237,385	-1%	NM	37	50,534,790	37	48,901,869	3%
GA	10	274,651,122	10	255,493,723	7%	NE	38	39,104,287	39	35,516,505	9%
SC	11	262,995,007	11	247,722,550	6%	CT	39	38,090,207	38	35,879,692	6%
AL	12	252,871,816	14	231,802,448	8%	ME	40	31,823,602	40	30,631,728	4%
KY	13	248,071,282	13	234,303,755	6%	MT	41	29,956,540	41	27,583,894	8%
PA	14	246,555,534	12	234,945,069	5%	RI	42	23,355,637	42	22,593,260	3%
NC	15	234,966,344	15	216,889,030	8%	HI	43	21,400,480	43	21,063,460	2%
MO	16	208,785,825	16	180,038,768	14%	SD	44	18,744,726	44	17,303,573	8%
OK	17	192,642,379	17	179,114,866	7%	NH	45	16,270,322	45	15,792,203	3%
LA	18	170,903,746	20	156,098,877	9%	AK	46	14,795,894	46	14,027,075	5%
WA	19	166,055,312	19	163,621,829	1%	WY	47	13,916,883	47	13,350,627	4%
NV	20	161,198,104	18	169,303,028	-5%	ND	48	12,479,481	48	10,515,903	16%
VA	21	157,974,527	21	147,003,823	7%	DE	49	10,936,956	49	10,391,298	5%
AZ	22	153,002,866	22	143,450,419	6%	VT	50	8,195,310	50	7,920,278	3%
MS	23	128,184,306	24	116,311,926	9%	DC	51	2,633,674	51	2,504,112	5%
OR	24	127,284,645	23	122,322,459	4%	PR	52	1,793,600	52	1,785,440	0%
AR	25	121,768,590	25	112,768,066	7%	VIR ISL	53	407,500	53	358,700	12%
WI	26	117,797,893	26	112,507,848	4%	GUAM	54	294,700	54	302,480	-3%
KS	27	101,921,733	28	94,285,791	7%	AM	55	7,000	55	0	100%
WV	28	97,449,564	27	94,782,536	3%	<b>TOTAL DU's</b>		<b>8,767,548,031</b>		<b>8,316,766,366</b>	<b>5%</b>

## National Poison Data System (Formerly known as Toxic Exposure Surveillance System) – Total Annual Mentions of Toxic Exposures

	Hydrocodone	Oxycodone
2001	15,191	9,480
2002	17,429	10,515
2003	19,578	11,254
2004	22,654	12,603
2005	22,229	13,191
2006	22,319	13,473
2007	24,558	15,069
2008	26,306	17,256
2009	27,753	18,396
2010	28,310	19,363



# NFLIS – State, local and federal cases reported

	Hydrocodone	Oxycodone
<b>2002</b>	9,106	7,993
<b>2003</b>	11,617	9,431
<b>2004</b>	16,299	13,342
<b>2005</b>	21,019	14,417
<b>2006</b>	24,798	17,733
<b>2007</b>	30,410	22,160
<b>2008</b>	33,611	28,340
<b>2009</b>	37,888	37,673
<b>2010</b>	39,138	47,193
<b>2011</b>	33,423	42,279

## National Forensic Laboratory Information System (NFLIS) – State, local and federal exhibits

	Hydrocodone	Oxycodone
<b>2002</b>	10,511	9,464
<b>2003</b>	13,699	11,311
<b>2004</b>	18,303	15,519
<b>2005</b>	23,537	17,057
<b>2006</b>	27,929	21,155
<b>2007</b>	34,449	26,479
<b>2008</b>	38,424	34,655
<b>2009</b>	44,077	46,590
<b>2010</b>	45,562	60,186
<b>2011</b>	39,226	53,788

## Drug Abuse Warning Network (DAWN) - Emergency Department Mentions

Year	Hydrocodone	Oxycodone
1994	9,320	4,069
1995	9,686	3,393
1996	11,419	3,190
1997	11,570	5,012
1998	13,611	5,211
1999	15,252	6,429
2000	20,098	10,825
2001	21,567	18,409
2002	25,197	22,397
2004*	39,844	41,701
2005	47,192	52,943
2006	57,550	64,888
2007	65,735	76,587
2008	89,051	105,214
2009	86,258	148,449

\*Changes in DAWN methodology were implemented in 2004 and thus the data from 2004 through 2009 cannot be compared to those of the previous years.



### Monitoring the Future, Annual Prevalence (Past Year Use) in Percent

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
<b>Oxycontin</b>										
8th Grade	1.3	1.7	1.7	1.8	2.6	1.8	2.1	2.0	2.1	1.8
10th Grade	3.0	3.6	3.5	3.2	3.8	3.9	3.6	5.1	4.6	3.9
12th Grade	4.0	4.5	5.0	5.5	4.3	5.2	4.7	4.9	5.1	4.9
<b>Vicodin</b>										
8th Grade	2.5	2.8	2.5	2.6	3.0	2.7	2.9	2.5	2.7	2.1
10th Grade	6.9	7.2	6.2	5.9	7.0	7.2	6.7	8.1	7.7	5.9
12th Grade	9.6	10.5	9.3	9.5	9.7	9.6	9.7	9.7	8.0	8.1

*From 2010 to 2011, there was a statistically significant decrease (1.8%) for 10th graders in past year use of Vicodin.*

## National Survey on Drug Use and Health – Lifetime nonmedical users of hydrocodone and oxycodone

Year	Hydrocodone Products	Oxycodone Products
2002	13,952,000	10,151,000
2003	16,808,000	11,538,000
2004	17,734,000	11,925,000
2005	18,875,000	12,029,000
2006	20,755,000	12,858,000
2007	21,335,000	13,055,000
2008	22,838,000	13,759,000
2009	23,543,000	15,281,000
2010	24,093,000	15,553,000



# State Ranking - Oxycodone

## Total Dosage Units Sold to Retail January 1, 2010 – December 31, 2011

2011			2010		% CHANGE 2010 to 2011
STATE	RANK	TOTAL DOSAGE UNITS	RANK	TOTAL DOSAGE UNITS	
FL	1	525,338,986	1	650,885,860	-24%
PA	2	311,529,433	2	288,870,043	7%
NY	3	299,937,485	4	266,896,986	11%
CA	4	295,022,496	5	261,181,184	11%
OH	5	289,383,062	3	282,936,529	2%
NC	6	222,189,039	6	201,693,238	9%
NJ	7	195,014,871	7	179,311,163	8%
AZ	8	173,034,663	8	154,633,084	11%
TN	9	158,340,886	11	141,889,292	10%
WA	10	153,748,970	9	151,249,822	2%
MA	11	151,947,593	10	146,314,057	4%
MD	12	149,086,425	12	141,639,892	5%
GA	13	142,133,490	13	125,986,084	11%
VA	14	131,740,301	14	118,068,618	10%
CO	15	112,194,642	17	100,227,545	11%
MO	16	109,876,292	18	99,979,350	9%
WI	17	108,480,463	16	100,329,263	8%
OR	18	107,116,456	15	101,389,306	5%
KY	19	94,901,418	19	81,873,088	14%
IN	20	90,455,351	20	80,726,827	11%
MI	21	82,434,611	21	73,164,053	11%
SC	22	79,359,293	23	71,450,580	10%
MN	23	76,127,137	24	69,549,000	9%
CT	24	74,439,138	22	71,531,918	4%
NV	25	70,560,182	25	63,270,105	10%
TX	26	69,676,107	26	62,437,942	10%
AL	27	61,157,797	28	51,216,443	16%
OK	28	57,706,857	27	52,363,292	9%

2011			2010		% CHANGE 2010 to 2011
STATE	RANK	TOTAL DOSAGE UNITS	RAN K	TOTAL DOSAGE UNITS	
LA	29	56,074,553	29	49,599,949	12%
UT	30	50,697,974	30	47,895,830	6%
NM	31	48,896,260	31	45,697,500	7%
IL	32	47,700,128	33	42,805,010	10%
WV	33	45,830,170	32	42,911,440	6%
AR	34	42,524,552	34	39,873,970	6%
KS	35	41,646,268	36	37,315,942	10%
DE	36	39,956,010	35	37,620,204	6%
ME	37	35,748,190	37	34,383,060	4%
NH	38	30,851,640	38	29,799,340	3%
MS	39	28,293,808	40	24,573,192	13%
IA	40	27,996,044	39	25,805,582	8%
RI	41	20,227,440	42	18,148,220	10%
HI	42	20,153,440	41	18,897,498	6%
ID	43	17,952,864	45	15,583,792	13%
MT	44	17,228,940	43	16,533,080	4%
NE	45	17,225,401	44	16,154,094	6%
AK	46	13,325,196	48	12,287,550	8%
PR	47	12,810,809	46	12,525,590	2%
VT	48	12,534,921	47	12,422,380	1%
DC	49	9,269,620	49	8,839,300	5%
WY	50	9,016,202	50	8,530,680	5%
SD	51	8,535,958	51	8,025,872	6%
ND	52	7,632,423	52	6,598,122	14%
GUAM	53	511,440	53	463,800	9%
VR ISL	54	288,500	54	301,080	-4%
AM SAM	55	42,800	55	50,200	-17%
TOTAL DU's		5,055,904,995		4,804,706,841	5%



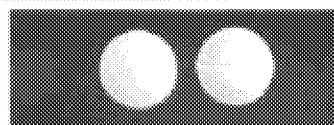
# OxyContin<sup>®</sup> (Schedule II)

- Controlled release formulation of Schedule II oxycodone
  - The controlled release method of delivery allows for a longer duration of drug action so it contains much larger doses of oxycodone
  - Abusers easily compromise the controlled release formulation by crushing the tablets for a powerful morphine-like high
  - Street Slang: “Hillbilly Heroin”
  - 10, 15, 20, 30, 40, 60, 80mg available
- Effects:
  - Similar to morphine in effects and potential for abuse/ dependence
- Street price: Approx. \$80 per 80mg tablet
- Since 2002, use among 12th graders has remained between approximately 4% and 5%\*

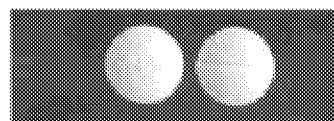
\*SOURCE: 2007 Monitoring the Future study released April 2008

# Other Oxycodone Products

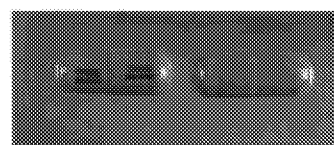
Percocet



**Trade Name: Percocet-Demi**  
Controlled Ingredient: oxycodone hydrochloride 2.25 mg and  
oxycodone terephthalate 0.99 mg  
Other Ingredients: aspirin, 325 mg



**Trade Name: Percodan**  
Controlled Ingredient: oxycodone hydrochloride 4.5 mg and  
oxycodone terephthalate 0.38 mg  
Other Ingredients: aspirin, 325 mg



**Trade Name: Tylox**  
Controlled Ingredient: oxycodone hydrochloride 4.5 mg and  
oxycodone terephthalate .38 mg  
Other Ingredients: Acetaminophen, 500 mg



**Trade Name: Percocet**  
Controlled Ingredient: oxycodone hydrochloride, 5 mg  
Other Ingredients: Acetaminophen, 325 mg

Roxicodone





# Opiates v. Heroin

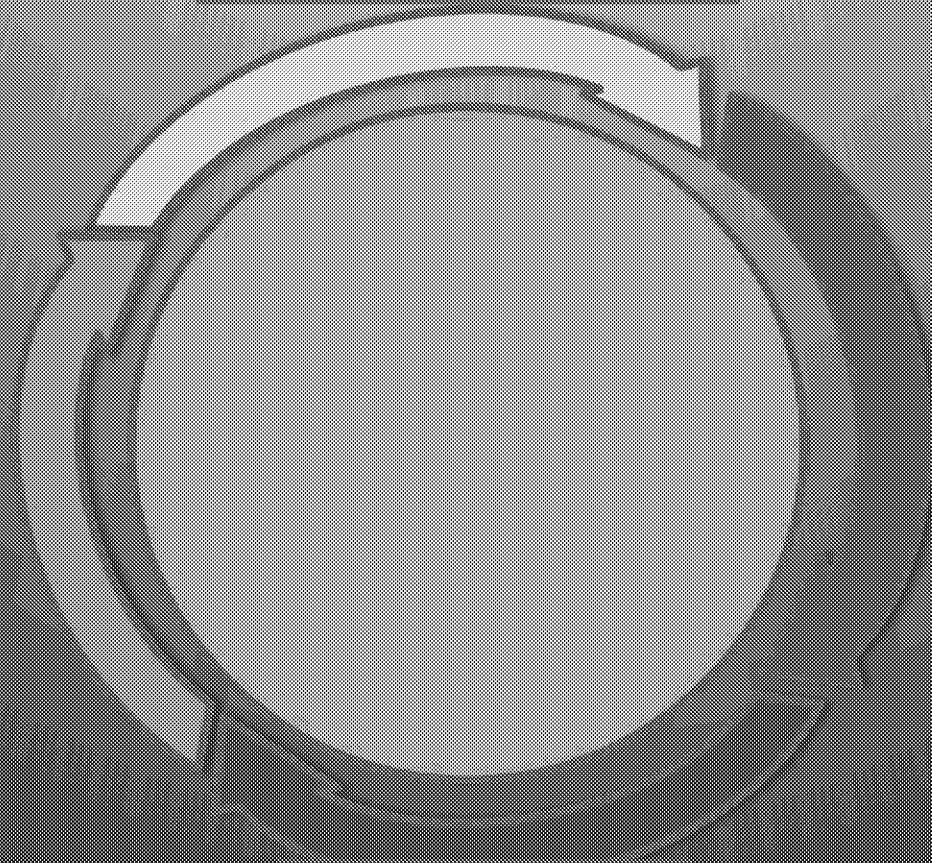


# Circle of Addiction & the Next Generation

Oxycodone  
Combinations

Percocet®

\$7-\$10/tab



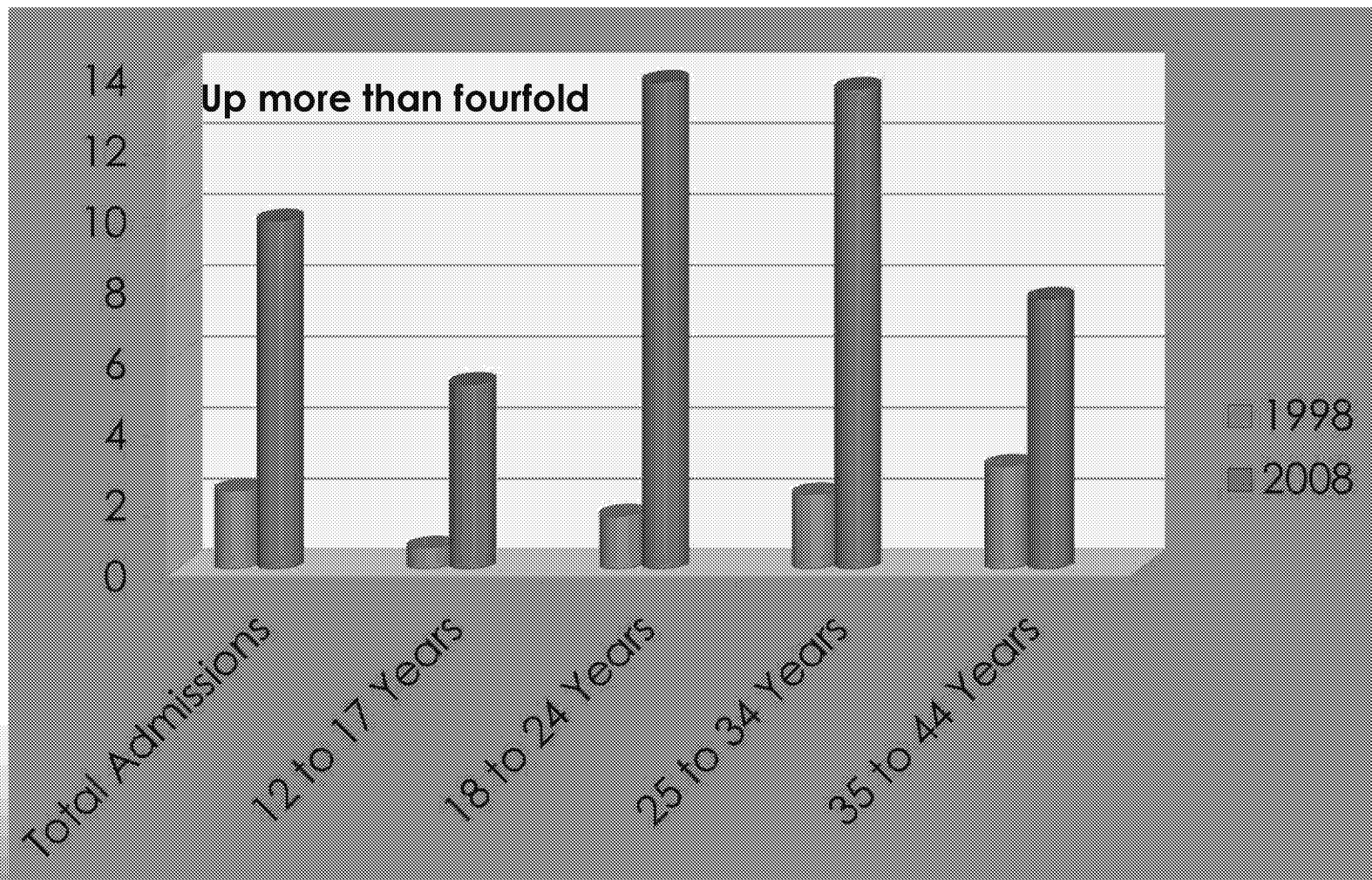
OxyContin®  
\$80/tab

Roxicodone®  
Oxycodone IR  
15mg, 30mg  
\$30-\$40/tab

Hydrocodone  
Lorcet®  
\$5-\$7/tab

Heroin  
\$15/bag

# *Substance Abuse Treatment Admissions within Specific Age Groups That Reported Any Pain Reliever Abuse: 1998-2008*



Source: SAMSHA Treatment Episode Data Set, 1998-2008 released July 15, 2010

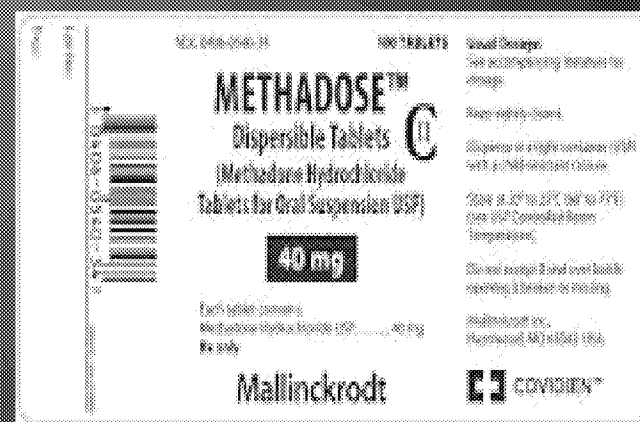


# Methadone- 5mg & 10mg



Mallinckrodt Pharmaceuticals 5 mg & 10mg

# Methadone 40 mg



# Bluefield Daily Telegraph

William "Randy" Deason  
Publisher

Thomas A. Colley  
Executive Editor

Samuelson Perry, Managing Editor

David Miller  
Sports Editor

Andy Hume  
City Editor

John G. Smith  
City Editor

John G. Smith  
City Editor

"Then he answered and spoke to me, saying, 'This is the word of the LORD to Zerubbabel, saying, 'Not by might nor by power, but by my spirit,' said the LORD of hosts.'"

(Zechariah 4:6 ARV)

## Overdose deaths Prescription drugs take deadly toll in WV

**A**n alarming new study has found that prescription drugs killed more people in West Virginia in 2016 than illegal drugs. According to the report, nine out of the 10 accidental overdose deaths reported in the Mountain State involved prescription drugs. Researchers in a joint state-federal study came to the troubling conclusion after studying 432 accidental overdose autopsy reports, excluding suicides and overdoses, the Associated Press reported.

The report found that one-third of the prescription drugs taken during the fatal accidents were being used as a result of a prescription issued by a doctor within the last 30 days. The report found fewer than one in four of the deaths involved illegal narcotics.

Ann Hall, a Centers for Disease Control Epidemic Intelligence Service Officer for the West Virginia Department of Health and Human Resources, said there is a perception among some citizens that just because narcotics are legal and prescribed drugs, they are somehow safer.

The report found that methadone contributed to one of three deaths, or more than any other prescription drug. However, the report found that only 10 of the overdose victims were enrolled in a methadone clinic for drug-abuse treatment.

The report found that other opioid drugs frequently linked to accidental overdose deaths included hydrocodone

□ □ □

*We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.*

and oxycodone. The two narcotics contributed to one in five deaths. Morphine contributed to about one in seven deaths, the report found. Anti-anxiety drugs were found in 43 percent of the deaths.

While law enforcement officials have been fighting the illegal drug scourge in our region for years, accidental overdose deaths associated with the misuse of prescription narcotics now represents an emerging epidemic for the Mountain State.

The alarming new study from the West Virginia Department of Health and Human Resources should be viewed as a call to action for our community. We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.

We must act now to educate our community. If we fail to act, the number of accidental overdose deaths in the state and the region could continue to rise. It will take a combined effort of public education and law enforcement cooperation to reduce these alarming statistics.



## editorials

# Rising methadone deaths

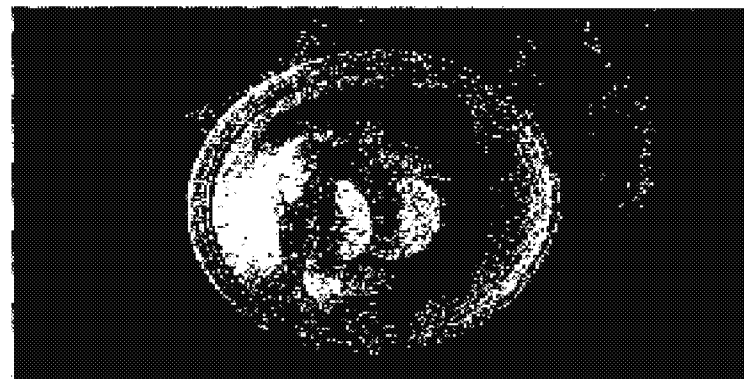
**Our view:** Baltimore public health officials are trying to find out if treatment for chronic pain sufferers accounts for increase in methadone overdoses

**T**HE JUNE LETTER FROM THE BALTIMORE HEALTH DEPARTMENT alerted physicians, nurses and other providers to a significant increase in methadone-related overdose deaths. The letter from Dr. Laura Herrera, a deputy city health commissioner, raised the possibility that the overdoses involved prescriptions for pain. It was a cautionary reminder that health care providers should educate their patients about the proper use of methadone and the lethal risks of taking extra doses.

Dr. Herrera was right to be concerned. Methadone-overdose deaths of city residents have risen from seven in 1995 to 74 in 2007. In 2007, the last year for which statistics are available, there was a 23 percent increase in such deaths over the previous year. The city deaths coincide with a similarly disturbing fivefold increase in methadone-related deaths nationally between 1999 and 2005. But proving that the use of methadone as a pain reliever caused these deaths isn't easy -- no one tracks how many physicians prescribe methadone to relieve chronic pain from cancer or arthritis, for example.

Prescribing methadone has been an accepted form of treatment for chronic pain for some time, according to pain specialists at Johns Hopkins Hospital and the University of Maryland Medical Center. They add that they have seen no methadone-related deaths among their patients. Methadone used for pain treatment is prescribed in pill form; its risk stems from the drug's potency and its lingering presence in the body once its pain-relieving function has ceased. An extra dose could slow down a patient's breathing, resulting in coma or death.

To identify the extent of the problem and the patients most at risk, the city Health Department has reviewed data from the medical examiner's office. It also has asked the quasi-public city agency that oversees drug treatment in Baltimore to cross-check methadone overdose victims against its patient rosters. That's a critical aspect of the review because it could uncover misuse, abuse or diversion of methadone



Methadone tablets in a cup. BALTIMORE SUN PHOTO: JEFF VORSCHEIMAN

from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.

At least 20 states have prescription monitoring programs that would identify indiscriminate prescribing, doctor-shopping and other abuses. A task force established this year in Maryland is studying the possibility of establishing a similar tracking system for methadone and other controlled substances.

Until then, Dr. Herrera and her colleagues at the Health Department have moved expeditiously and forthrightly to unravel this mystery. The results of their findings are the key to understanding and reversing this disturbing trend.

400 Greenley Road  
Sonoma, CA 95370

# The Union Democrat



THE MOTHER LODE'S LEADING INFORMATION SOURCE

## Report finds trends in child deaths

By ALISHA WYMAN  
*The Union Democrat*

Prescription drug abuse, suicide and vehicle accidents were the most prevalent causes of death last year among children and young adults in Tuolumne County, according to a recently-released report.

The Child Death Review Team, made up of officials from the Sheriff's Office, the Sonoma Police Department, the Public Health Department, Child Welfare Services and other agencies, examined 11 deaths of youths through age 25. Most were teens and young adults.

One of the concerning trends was a

rise in abuse of prescription drugs, particularly methadone, Sheriff's spokesman Lt. Dan Bressler said.

"What we're finding is even small amounts of methadone mixed with alcohol can cause death," he said. "It doesn't take much."

Three young people died of accidental overdose in 2007, two of which

involved a mixture of alcohol and methadone, a painkiller also used to help with withdrawals of harsher drugs such as heroin.

Tuolumne County isn't the only area to see a rise in prescription drug abuse, said Dr. Todd Stolp, county public health officer.

"It's a national issue, but we're in the

process of identifying the extent of the problem and how to address the problem," he said.

There were three suicides in 2007. The number could be higher, however, because there were some drug-related cases in which there wasn't enough

SEE DEATHS/



# WHY IS IT ALSO USED AS AN ANALGESIC??????

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?

# Overdose...Why?

- Patients not taking the drug as directed
- Physicians not properly prescribing the drug
- Non medical users ingesting with other substances
- Opiate naive

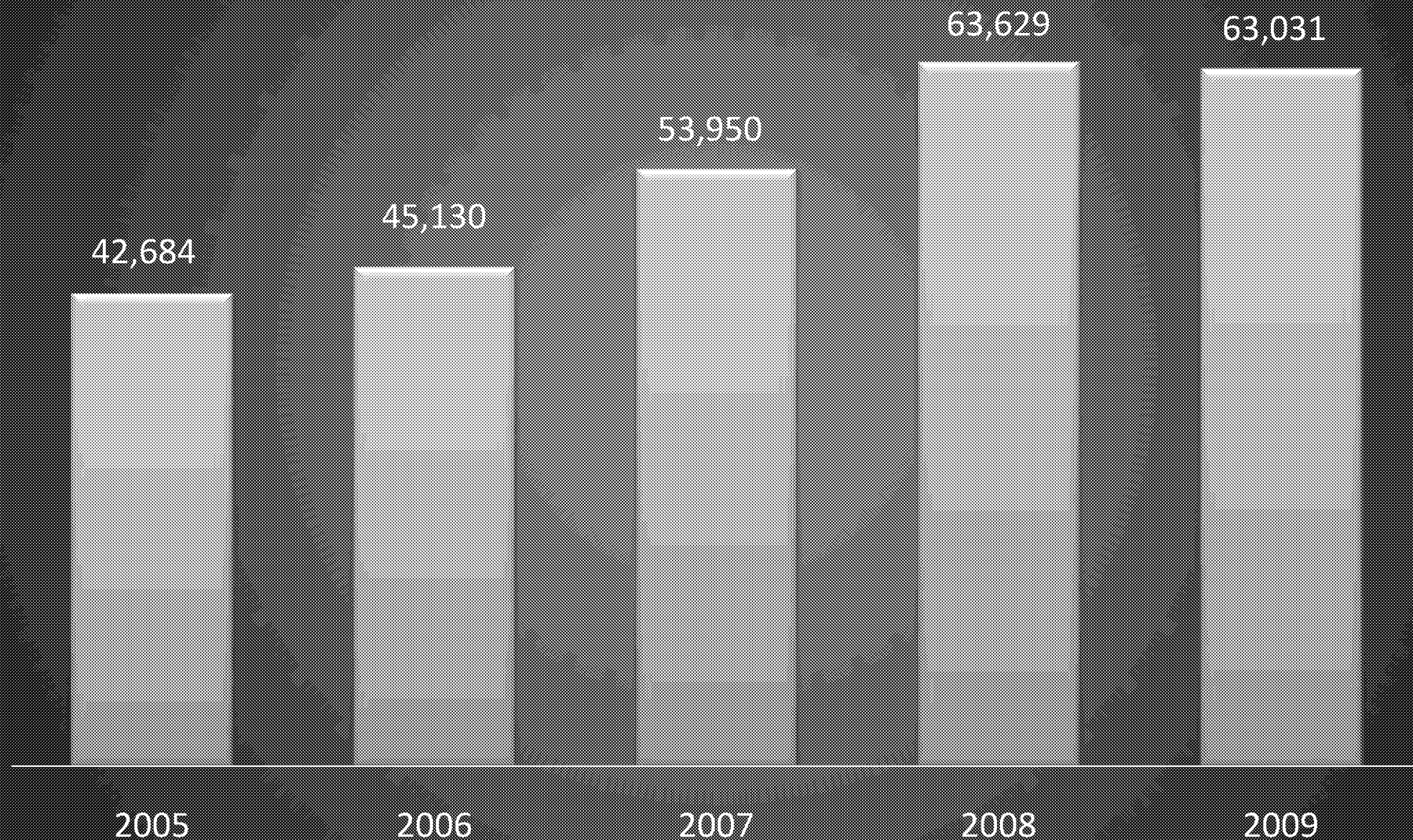


# Methadone – Drug Interactions

---

- CNS depressants  
(e.g., alcohol, anesthetics, sedatives, other opioids) -  
Additive effect
- Antiretroviral drugs have variable interactions
- CYP3A4 inhibitors (some antifungal agents, macrolide antibiotics, and SSRIs) – Inhibits elimination
- Grapefruit juice inhibits methadone elimination
- Smoking enhances (CYP1A2) methadone elimination
- Self-inducer – Enhances (3.5 fold between 1<sup>st</sup> dose and steady state) its own elimination
- Anticonvulsants – Enhances methadone elimination

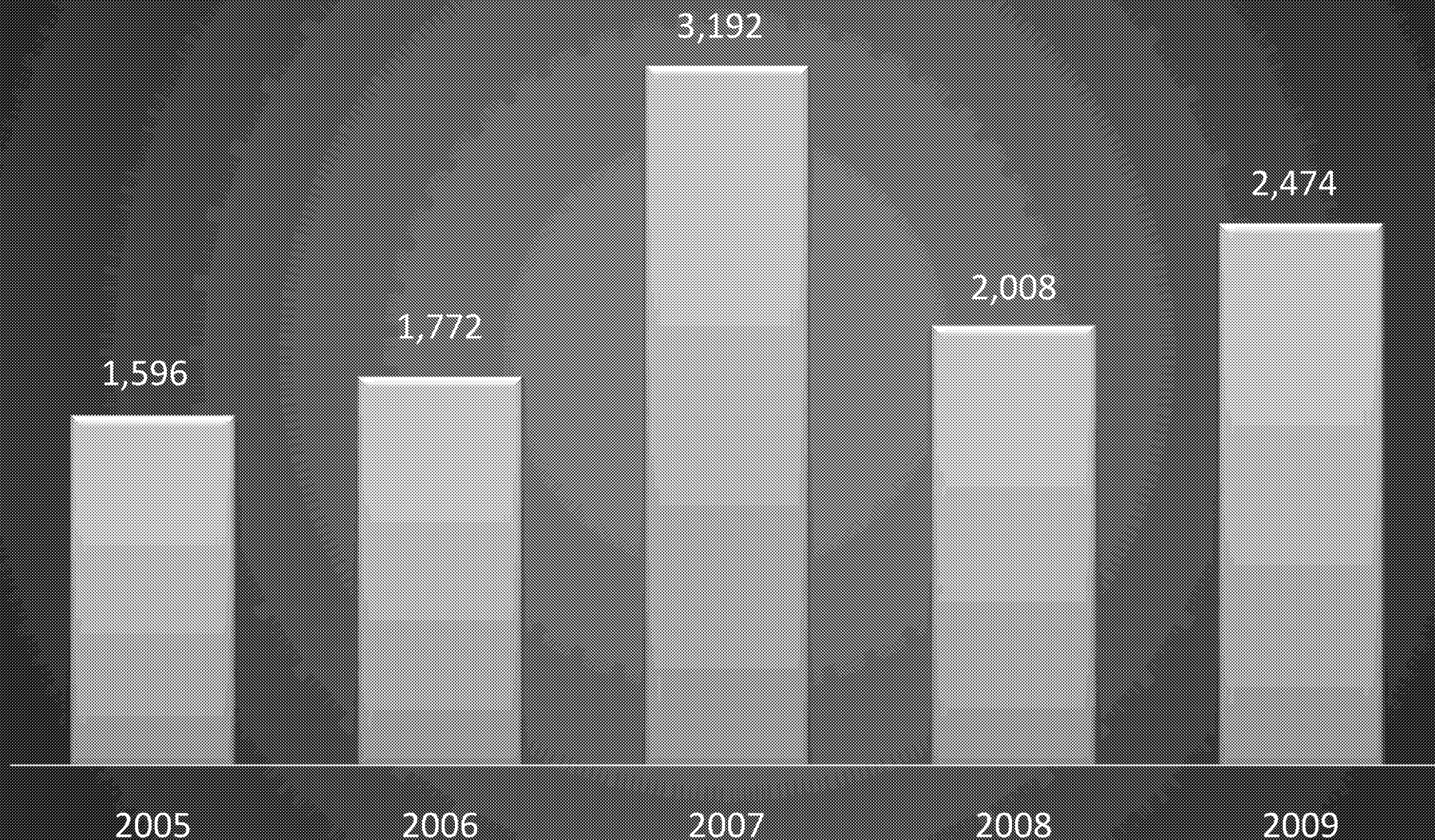
# ER visits involving Methadone



Source: Drug Abuse Warning Network (DAWN) 2009: August 2011

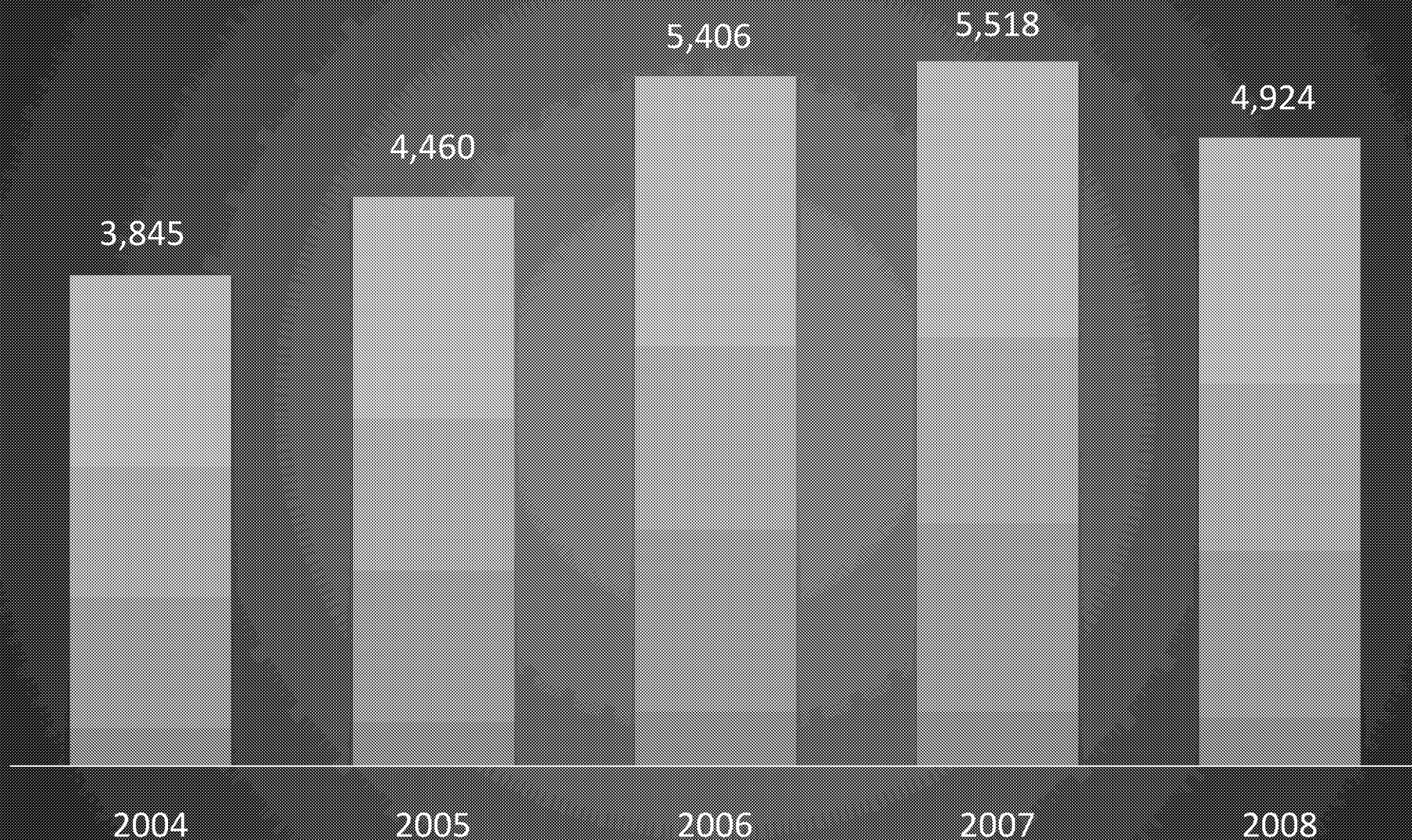


# Suicide attempts involving Methadone



Source: Drug Abuse Warning Network (DAWN) 2009: August 2011

# Deaths involving Methadone

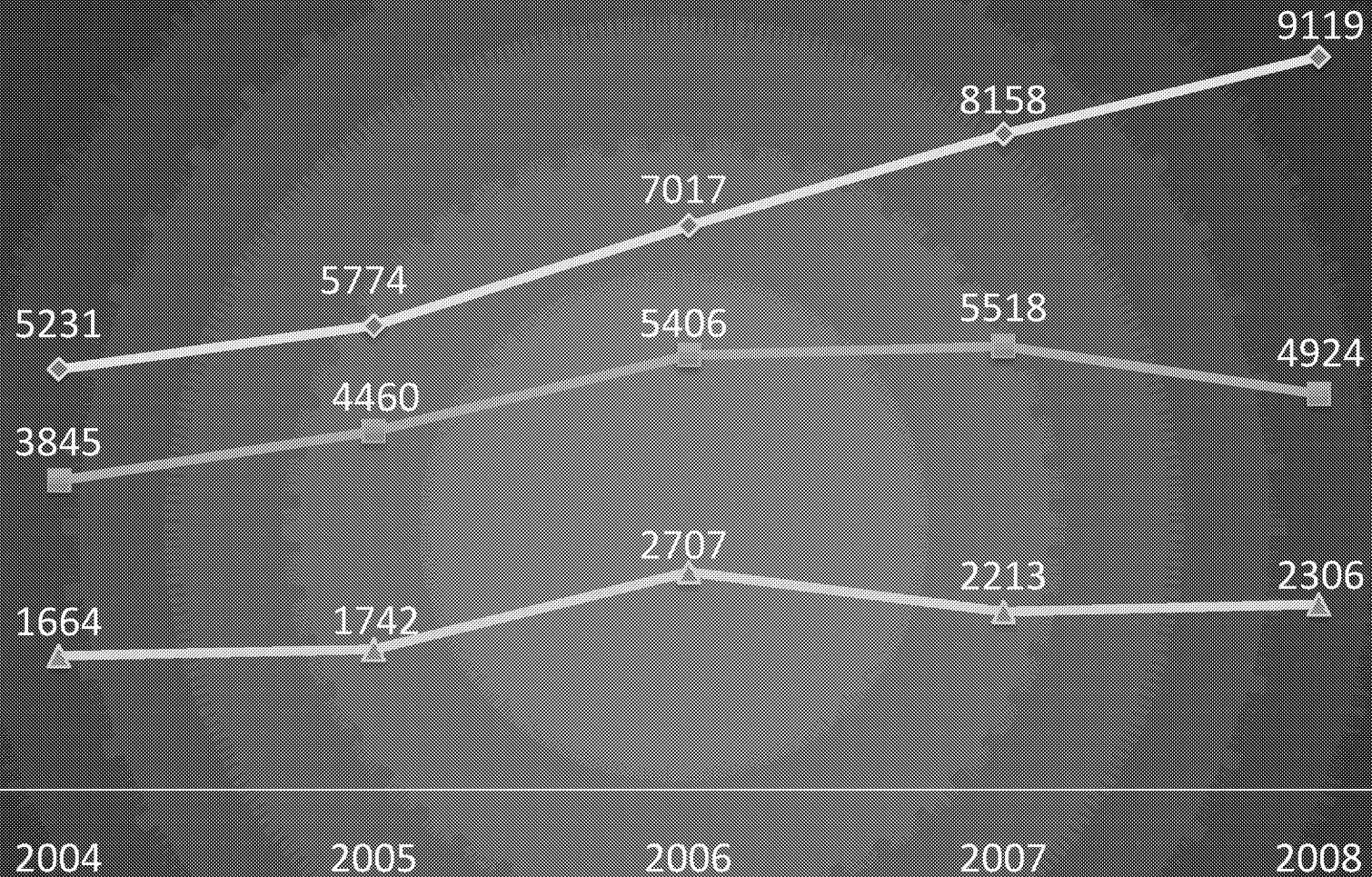


Source: NCHS Data Brief #81, December 2011



Case: 1:17-md-02804-DAP Doc #: 2816-3 Filed: 10/14/19 99 of 188 PageID #: 425072

# Opioid analgesic involved in deaths



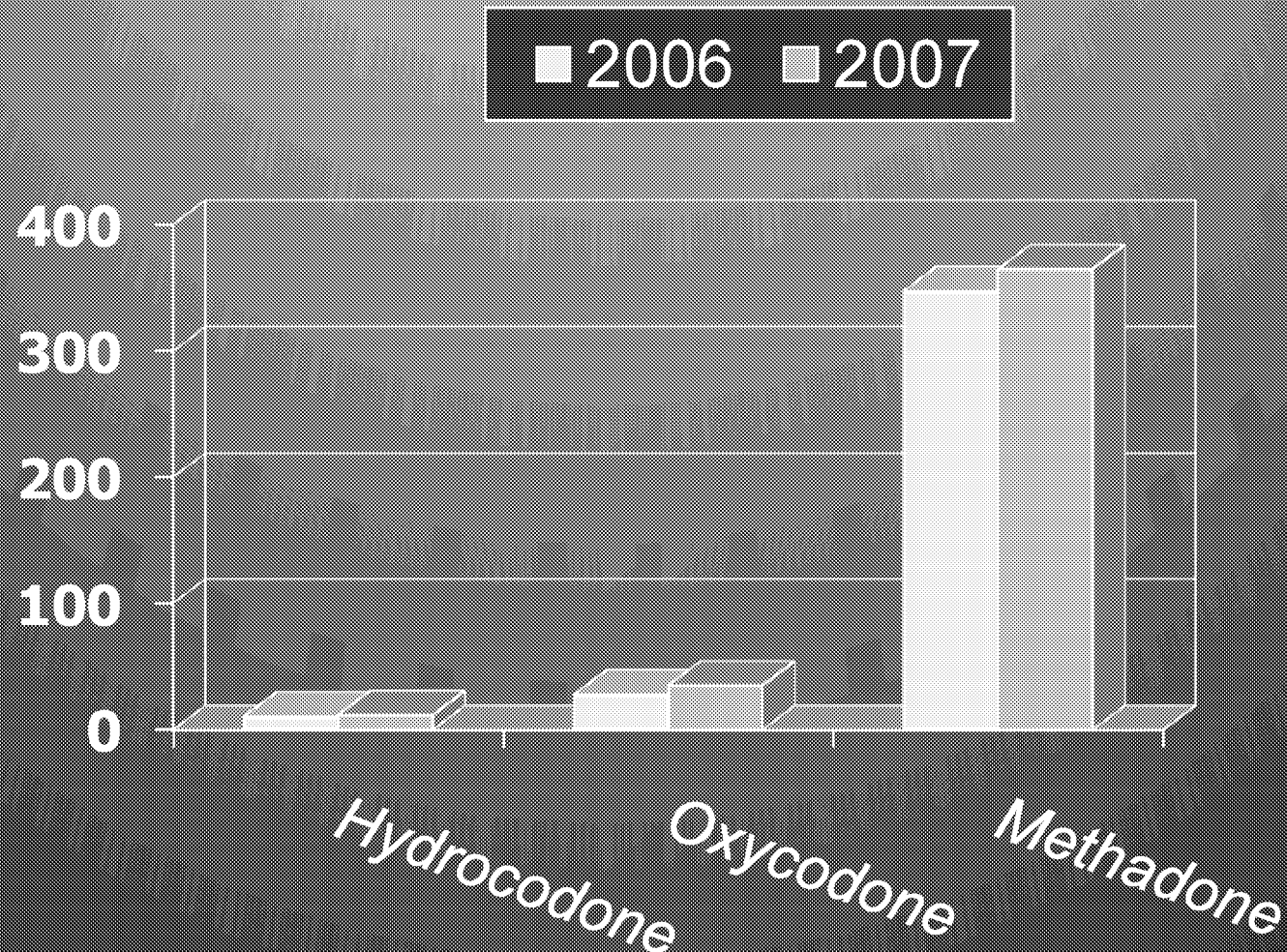
- ◆ Natural and semi-synthetic opioid deaths
- Methadone deaths
- ▲ Synthetic opioid deaths

Source: NCHS Data Brief #81, December 2011

# Deaths/100,000 Prescriptions in Florida

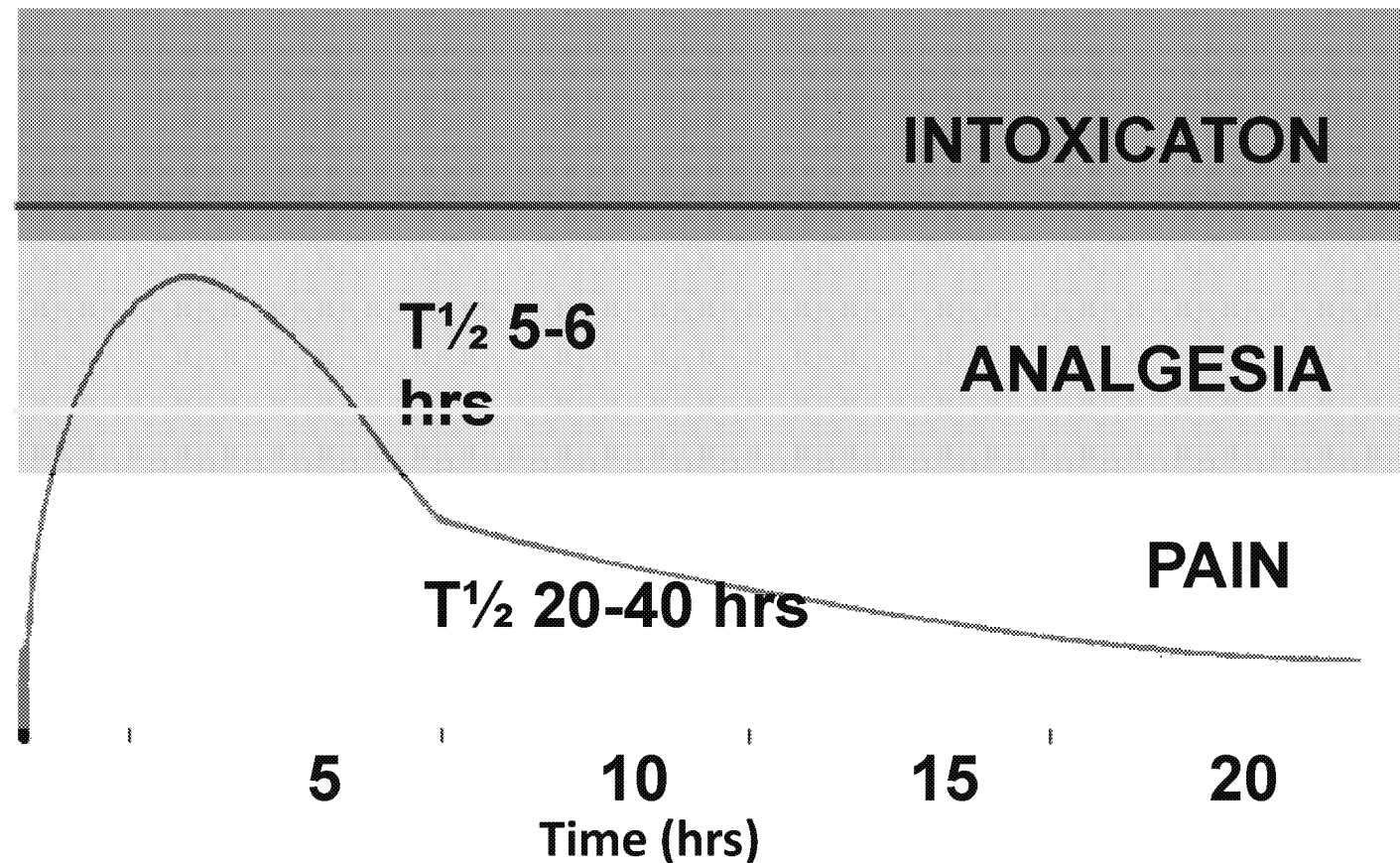
Source: FDLE and NPA Plus™

Deaths/100,000  
Prescriptions





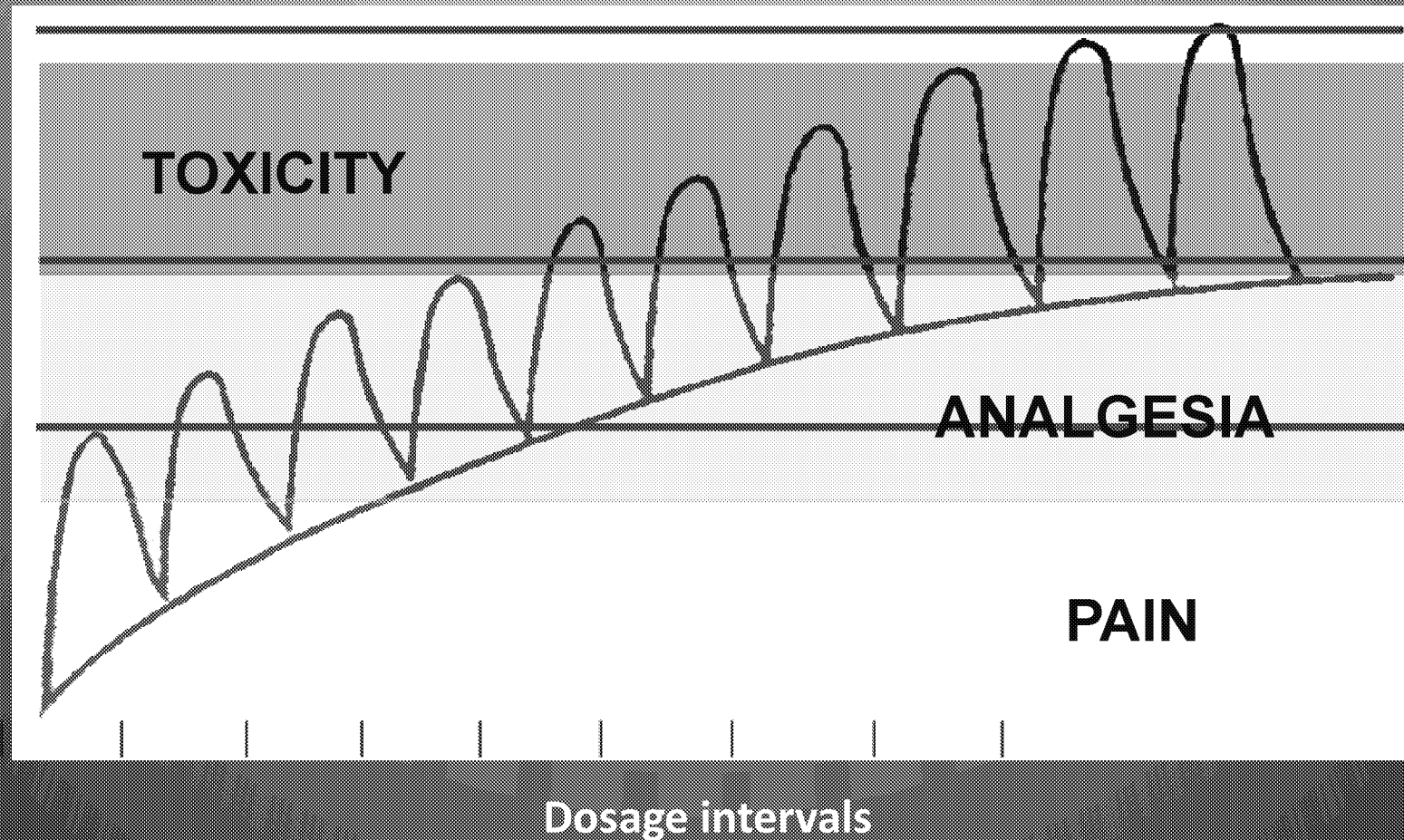
# Methadone Single Dose Kinetics



Ref: Nilsson MI, et al. Acta anaesth. scand 1982, Suppl 74, 66-69

Source: Resource Manual for CME course entitled "*Prescribing Opioids for Chronic Pain*" –  
Offered by the New England Chapters of the American Society of Addiction Medicine with support  
from CSAT, SAMHSA

# Fixed Methadone Dose Interval



Ref: Nilsson MI, et al. Acta anaesth. scand 1982, Suppl 74, 66-69

**Source:** Resource Manual for CME course entitled *"Prescribing Opioids for Chronic Pain"* – Offered by the New England Chapters of the American Society of Addiction Medicine with support from CSAT, SAMHSA



# One Pill can Kill



CE Article: JACOME, OML, ACEP | CE credit for this article

By Jonathan J. Lipman, PhD

## THE METHADONE POISONING “Epidemic”

Increasing use of  
Methadone as a  
pain killer  
may be  
fueling a  
disturbing  
increase  
in deaths  
related to this  
potent drug.

Name \_\_\_\_\_ Date \_\_\_\_\_  
Address \_\_\_\_\_

### Rx

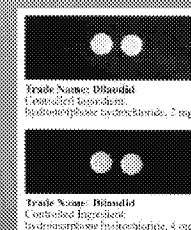
**D**eath and morbidity associated with methadone treatment has increased dramatically in recent years, largely in the population prescribed this drug for pain control rather than addiction maintenance. Inadvertent overdose is becoming increasingly common, likely in part because the drug's acute pain-relieving effect lasts only 4 to 6 hours, yet it has a very long and variable plasma half-life of 24 to 36 (in some studies 15 to 55) hours, is stored in body tissues, and toxic accumulation occurs with too-frequent consumption. Adverse effects are most common in patients treated with methadone in combination with other drugs. Both cardiac and respiratory systems are vulnerable targets for the drug's toxic actions, and other co-administered drugs can interactively increase the risk of death through a variety of mechanisms including direct central nervous system depression of respiration, idiosyncratic respiratory vulnerabilities, and lethal cardiac arrhythmias. Idiosyncratic factors also play a part in methadone's cardiac toxicity, and risk factors are well characterized, though perhaps not sufficiently widely known and understood by key stakeholders. The recent change in FDA labeling requirements for the drug—and the November 2006 posting of a government warning regarding its use in pain treatment—has not yet reduced morbidity and mortality associated with methadone as reported in the MedWatch database for the first quarter of 2007.

# Other Narcotics

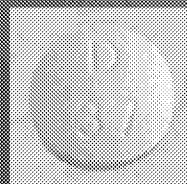
## Fentanyl



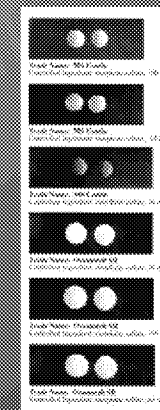
## Hydromorphone



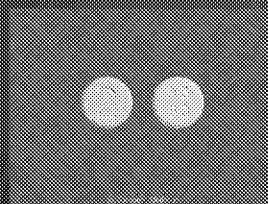
## Meperidine



## Morphine



## Codeine



## Propoxyphene





# Fentanyl



- Fentanyl Patches
- Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- Fentanyl is 100 times more potent than morphine
- Intended to be used for chronic cancer pain & only for people who are tolerant to prescription opioid (narcotic) pain medicines
- Abused for its intense euphoric effects

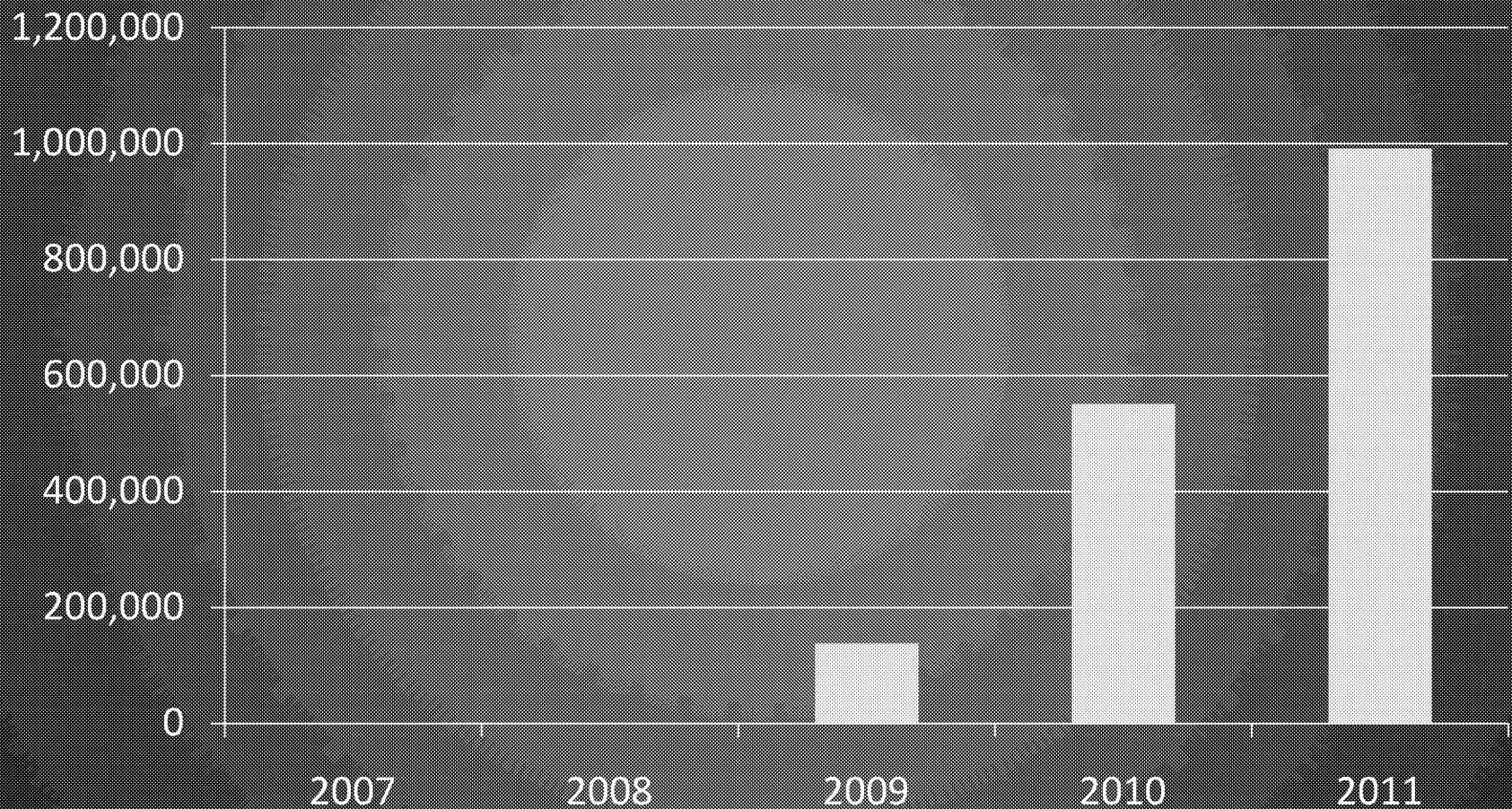


**Fentora®**

**Actiq®**



# Tapentadol Prescriptions



Source: IMS Health National Prescription Audit Plus downloaded 6/5/2012



# Narcotic Addiction Treatment Options

- Office based (DATA-2000)
- Methadone treatment programs

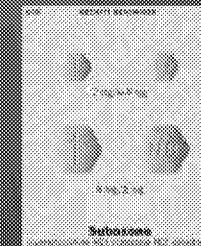
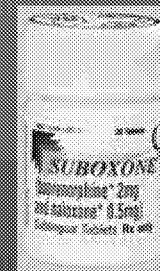
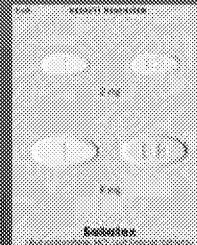
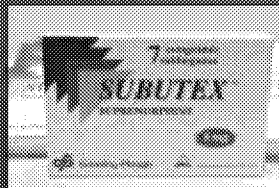
# Methadone Clinics

- 1247 clinics operating nationwide



# Other FDA Approved Drugs for Narcotic Addiction Treatment

- Schedule III
  - Buprenorphine – Drug Code 9064
    - Subutex (sublingual, single entity tablet)
    - Suboxone (sublingual, buprenorphine/naloxone tablet)



# DATA Waive Physicians

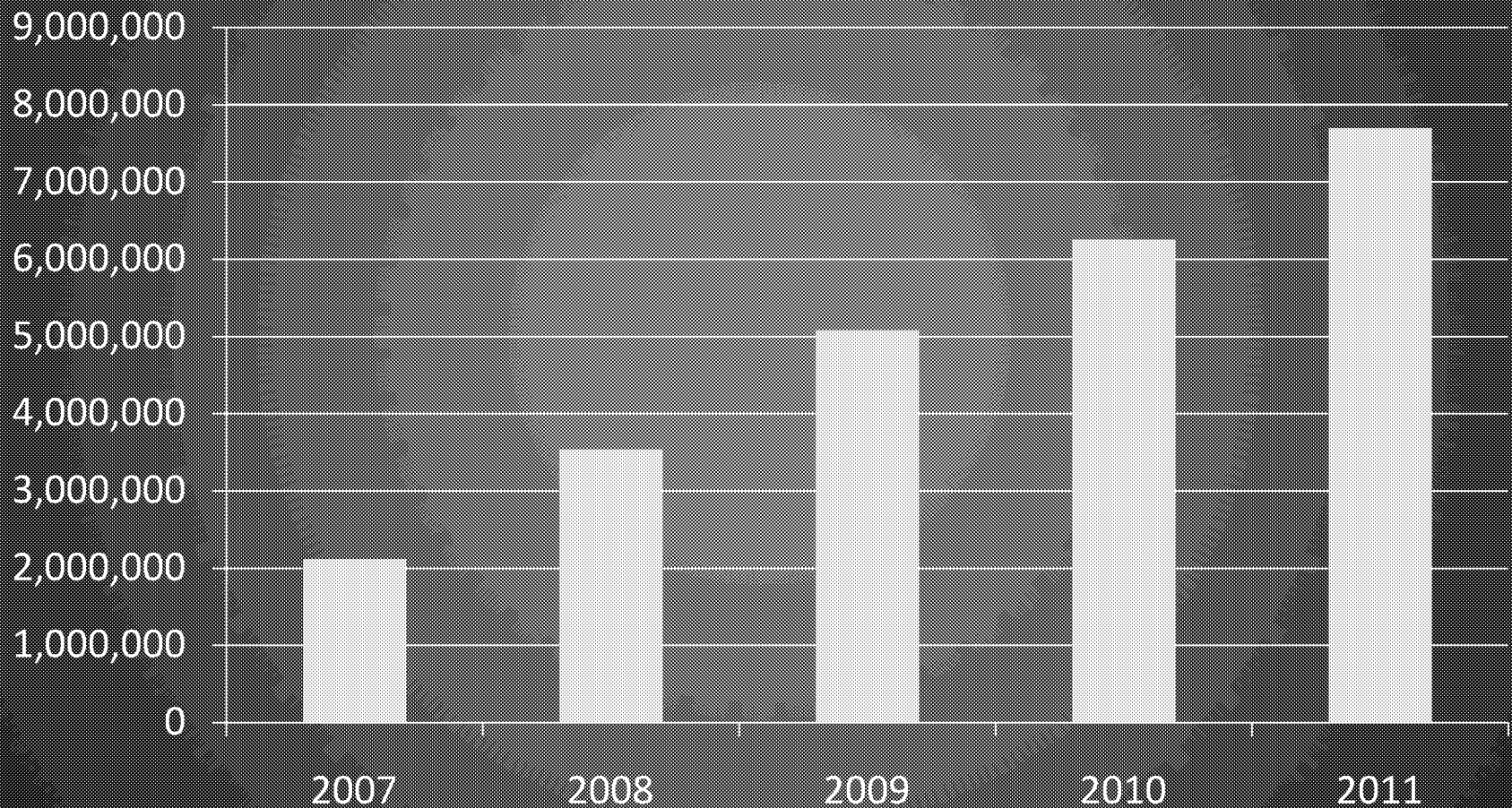
- Current (6/5/12) CSAT population of certified DATA Waive Physicians:
  - DW-30 Physicians- 17, 397
  - DW-100 Physicians- 5,984
- Total: **23,381**



# DATA Waive Physicians

- Current (6/5/2012) DEA population of certified DATA Waive Physicians:
  - DW-30 Physicians - 15,867
  - DW-100 Physicians - 5,430
  - Military Physicians – 45
- Total **21,342**
- Difference between CSAT & DEA Population:
  - **2,039**

# Buprenorphine Prescriptions



Source: IMS Health National Prescription Audit Plus downloaded 6/5/2012



# NFLIS Data

- From January 2001 to June 2011 buprenorphine reports increased more than 900-fold (from 6 to 5,427).
- The largest increase of Buprenorphine reports during the same time period was in the Northeast from no reports to 4.8 reports per 100,000 persons.



# NFLIS Data

Reporting period:

January 2011 through June 2011

Buprenorphine*	4,836 reports	7.31%
----------------	---------------	-------

\*3<sup>rd</sup> most reported Narcotic analgesic behind Oxycodone and Hydrocodone.



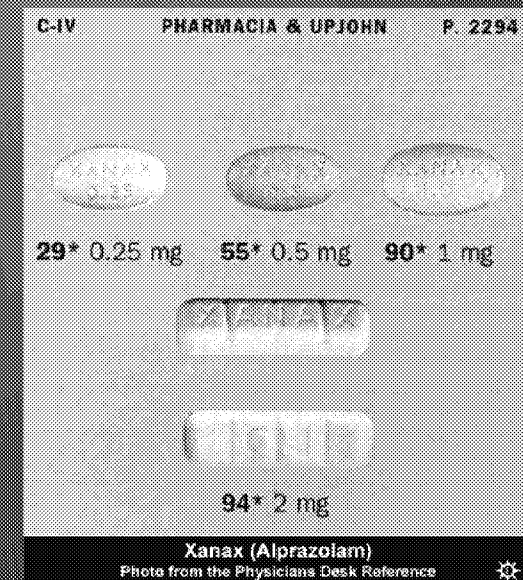
# Alprazolam Xanax<sup>®</sup> (Z-bars)

C-IV

- Drug abusers often prefer alprazolam due to its rapid onset and longer duration of action
- Alprazolam was ranked third in the number of prescriptions for controlled substances in 2003, 2004, 2005 and 2006\*
- For all sales of generic pharmaceuticals, alprazolam was ranked 7th\*\*

\* Source IMS Health

\*\* Source Verispan VONA



# Other Controlled Substances

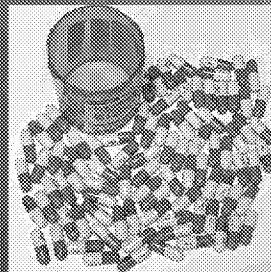


- Phentermine C-IV
- Phendimetrazine C-III



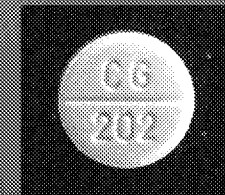
– Bontril®

- Amphetamines



– Adderall C-II

– Methylphenidate C-II



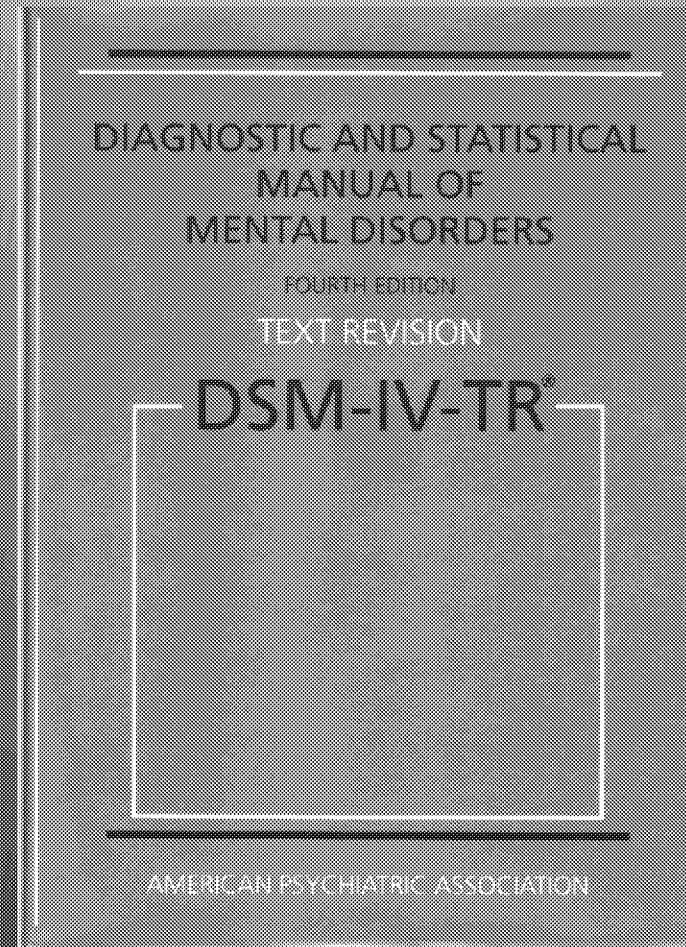
• Ritalin®

• Concerta®





# REQUIRED READING



## Attention-Deficit and Disruptive Behavior Disorders

### Attention-Deficit/Hyperactivity Disorder

#### Diagnostic Features

Some hyperactive-impulsive or inattentive symptoms that cause impairment must have been present before age 7 years, although many individuals are diagnosed after the symptoms have been present for a number of years, especially in the case of individuals with the Predominantly Inattentive Type (Criterion B)

A1c). There may be frequent shifts from one uncompleted activity to another. Individuals diagnosed with this disorder may begin a task, move on to another, then turn to yet something else, prior to completing any one task. They often do not follow through on requests or instructions and fail to complete schoolwork, chores, or other duties (Criterion A1d). Failure to complete tasks should be considered in making this diagnosis only if it is due to inattention as opposed to other possible reasons (e.g., failure to understand instructions, defiance). These individuals often have difficulties organizing tasks and activities (Criterion A1e). Tasks that require sustained mental effort are experienced as unpleasant and markedly aversive. As a result, these individuals typically avoid or have a strong dislike for activities that demand sustained self-application and mental effort or that require organizational demands or close concentration (e.g., homework or paperwork) (Criterion A1f). This avoidance must be due to the person's difficulties with attention and not due to a primary oppositional attitude, although secondary oppositionalism may also occur. Work habits are often disorganized and the materials necessary for doing the task are often scattered, lost, or carelessly handled and damaged (Criterion A1g). Individuals with this disorder

- Fails to give close attention to details...make careless mistakes in schoolwork, work
- Difficulty sustaining attention in tasks
- Does not seem to listen when spoken to
- Does not follow through on instructions
- Difficulty organizing tasks
- Often loses things necessary for tasks
- Easily distracted
- Forgetful

- (h) is often easily distracted by extraneous stimuli
- (i) is often forgetful in daily activities

- (2) six (or more) of the following symptoms of **hyperactivity-impulsivity** have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

#### Hyperactivity

- (a) often fidgets with hands or feet or squirms in seat
- (b) often leaves seat in classroom or in other situations in which remaining

- Fidgets
- Can't remain seated
- Restlessness
- Difficulty awaiting turn
- Often interrupts or intrudes

- B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.
- C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).



that require and poor understanding, typical of self others as for. Family especially believe parent-child

with successful treatment. On average, individuals with Attention-Deficit/Hyperactivity Disorder obtain less schooling than their peers and have poorer vocational achievement. Also, on average, intellectual level, as assessed by individual IQ tests, is several points lower in children with this disorder compared with peers. At the same time, great variability in IQ is evidenced: individuals with Attention-Deficit/Hyperactivity Disorder may show intellectual development in the above-average or gifted range. In its severe form, the disorder is markedly impairing, affecting social, familial, and scholastic adjustment. All three subtypes are associated with significant impairment. Academic deficits and school-related problems tend to be most pronounced in the types marked by inattention (Predominantly Inattentive and Combined Types), whereas peer rejection and, to a lesser extent, accidental injury are most salient in the types marked by hyperactivity and impulsivity (Predominantly Hyperactive-Impulsive and Combined Types). Individuals with the Predominantly Inattentive Type tend to be socially passive and appear to be neglected, rather than rejected, by peers.

A substantial proportion (approximately half) of clinic-referred children with Attention-Deficit/Hyperactivity Disorder also have Oppositional Defiant Disorder or Conduct Disorder. The rates of co-occurrence of Attention-Deficit/Hyperactivity Disorder with these other Disruptive Behavior Disorders are higher than with other mental disorders, and this co-occurrence is most likely in the two subtypes marked by hyperactivity-impulsivity (Hyperactive-Impulsive and Combined Types). Other associated disorders include Mood Disorders, Anxiety Disorders, Learning Disorders, and Communication Disorders in children with Attention-Deficit/Hyperactivity Disorder. Although Attention-Deficit/Hyperactivity Disorder appears in at least 50% of clinic-referred individuals with Tourette's Disorder, most individuals with Attention-Deficit/Hyperactivity Disorder do not have accompanying Tourette's Disorder. When the two disorders coexist, the onset of the Attention-Deficit/Hyperactivity Disorder often precedes the onset of the Tourette's Disorder.

There may be a history of child abuse or neglect, multiple foster placements, neurotoxin exposure (e.g., lead poisoning), infections (e.g., encephalitis), drug exposure in utero, or Mental Retardation. Although low birth weight may sometimes be associated with Attention-Deficit/Hyperactivity Disorder, most children with low birth weight do not develop Attention-Deficit/Hyperactivity Disorder, and most children with Attention-Deficit/Hyperactivity Disorder do not have a history of low birth weight.

**Associated laboratory findings.** There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clinical

## There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clinical assessment of Attention-Deficit/Hyperactivity Disorder

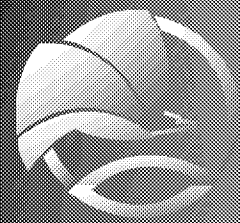
ire  
als  
sts  
lar  
its

There are no specific physical features associated with Attention-Deficit/Hyperactivity Disorder, although minor physical anomalies (e.g., hypertelorism, highly arched palate, low-set ears) may occur at a higher rate than in the general population. There may also be a higher rate of accidental physical injury.

### Specific Culture, Age, and Gender Features

Attention-Deficit/Hyperactivity Disorder is known to occur in various cultures, with variations in reported prevalence among Western countries probably arising more from different diagnostic practices than from differences in clinical presentation.

It is difficult to establish this diagnosis in children younger than age 4 or 5 years, because their characteristic behavior is much more variable than that of older children and may include features that are similar to symptoms of Attention-Deficit/Hyperactivity Disorder. Furthermore, symptoms of inattention in toddlers or preschool children are often not readily observed because young children typically experience few demands for sustained attention. However, even the attention of toddlers can be held in a variety of situations (e.g., the average 2- or 3-year-old child can typically sit with an adult looking through picture books). Young children with Attention-Deficit/Hyperactivity Disorder move excessively and typically are difficult to contain. Inquiring about a wide variety of behaviors in a young child may be helpful in ensuring that a full clinical picture has been obtained. Substantial impairment has been demonstrated in preschool-age children with Attention-Deficit/Hyperactivity Disorder. In school-age children, symptoms of inattention affect classroom work and academic performance. Impulsive symptoms may also lead to the breaking of familial, interpersonal, and educational rules. Symptoms of Attention-Deficit/Hyperactivity Disorder are typically at their most prominent during the elementary grades. As children mature, symptoms usually become less conspicuous. By late childhood and early adolescence, signs of excessive gross motor activity (e.g., excessive running and climbing, not remaining seated) are less common, and hyperactivity symptoms may be confined to fidgetiness or an inner feeling of jitteriness or restlessness. In adulthood, restlessness may lead to difficulty in participating in sedentary activities and to avoiding pastimes or occupations that provide limited opportunity for spontaneous movement (e.g., desk jobs). Social dysfunction in adults appears to be especially likely in those who had additional concurrent diagnoses in childhood. Caution should be exercised in making the diagnosis of Attention-Deficit/Hyperactivity Disorder in adults solely on the basis of the adult's recall of being inattentive or hyperactive as a child, because the validity of such retrospective data is often problematic. Although supporting information may not always be available, corroborating information from other informants (including prior school records) is helpful for improving the accuracy of the diagnosis.



# Ritalin® / Concerta® / Adderall

- Used legitimately to treat ADHD
- Used non-medically to get high and as an academic “performance-enhancer” to improve memory and improve concentration – gain the edge
  - Higher GPA
  - Higher SAT / ACT score
  - Get that scholarship



# QUOTAS/SHORTAGES

# Quotas

- DEA's mission is to prevent, detect, and investigate the diversion of pharmaceutical controlled substance from legitimate channels while ensuring an adequate and uninterrupted supply of pharmaceutical controlled substances to meet legitimate medical, commercial, and scientific needs.
- DEA is statutorily required to issue production material quota to the registered manufacturers on a yearly basis (21 USC 826).

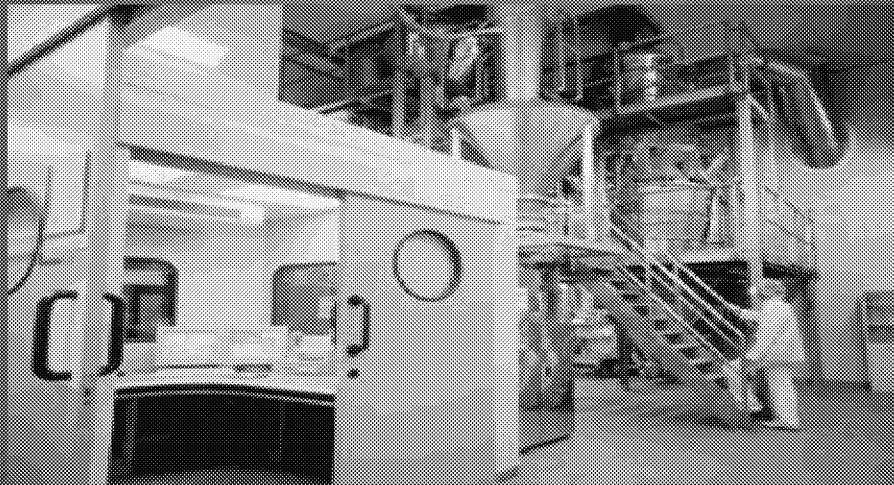


# Criteria in Determining Quota

- The manufacturer's current rate of disposal
- The trend of the national disposal rate during the preceding calendar year
- The manufacturer's production cycle and inventory position
- The economic availability of raw materials
- Yield and stability problems
- Emergencies such as strikes and fires
- Other factors.

# Quotas/Shortages

- DEA issued enough quota to the industry to meet the medical, commercial, and scientific needs.



- DEA has no statutory or regulatory authority relating to FDA manufacturing issues.



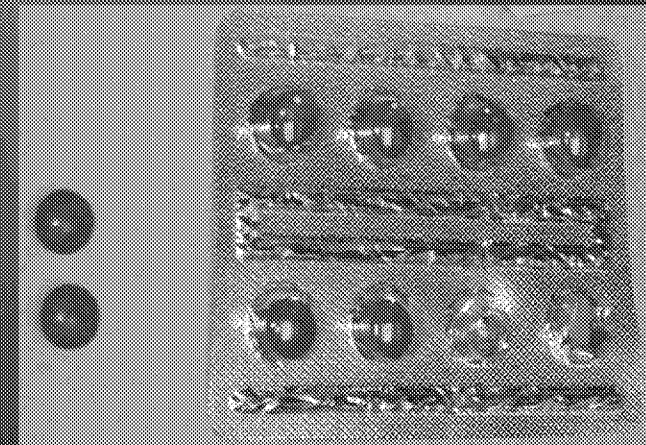


# ROBITUSSIN

Because Gatorade doesn't make you a flying robot in space.

# Dextromethorphan (DXM)

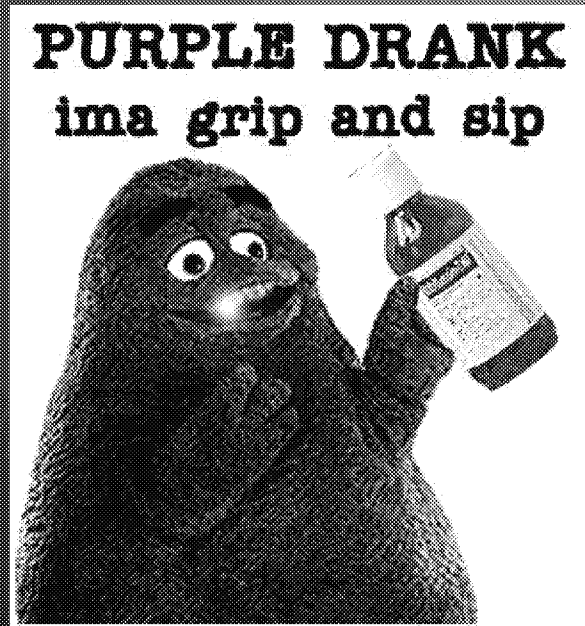
- Cough suppressant in over 125 OTC medications (e.g. Robitussin and Coricidin)
- Bulk form on the Internet
- At high doses, has Ketamine- and PCP-like effects
- Produces physical and psychological dependence
- Deaths associated with DXM abuse





# Cough Syrup Cocktails

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple Drank”







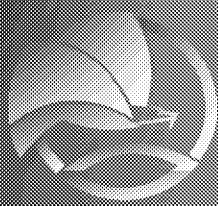
# Methods of Diversion

- Practitioners / Pharmacists
  - Illegal distribution
  - Self abuse
  - Trading drugs for sex
- Employee pilferage
  - Hospitals
  - Practitioners' offices
  - Nursing homes
  - Retail pharmacies
  - Manufacturing / distribution facilities
- Pharmacy / Other Theft
  - Armed robbery
  - Burglary (Night Break-ins)
  - In Transit Loss (Hijacking)
  - Smurfing
- Patients / Drug Seekers
  - Drug rings
  - Doctor-shopping
  - Forged / fraudulent / altered prescriptions
- The medicine cabinet / obituaries
- The Internet
- Pain Clinics



# Where are the Pharmaceuticals Coming From?

- Medicine Cabinet
- Internet
- Pain Clinics
- Doctor Shoppers; RX Fraud; Practitioner Diversion



# Prescription Fraud

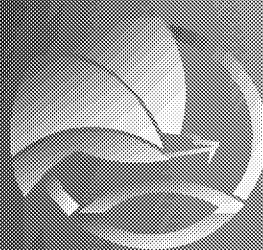
- **Fake prescriptions**

- Highly organized
- Use real physician name and DEA Registrant Number
  - Contact Information false or “fake office”
    - (change locations often to avoid detection)
- Prescription printing services utilized
  - Not required to ask questions or verify information printed

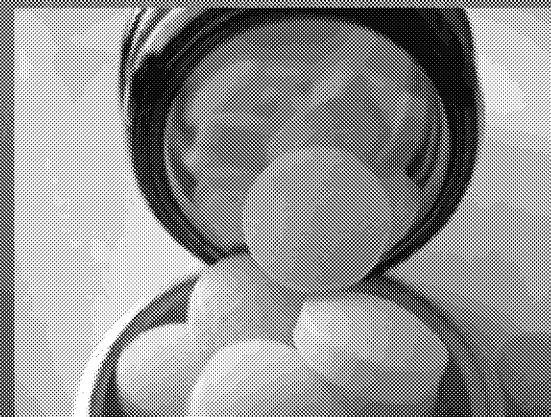
- **Stolen prescriptions**

- Forged
- “Smurfed” to a large number of different pharmacies





# Doctor Shopping

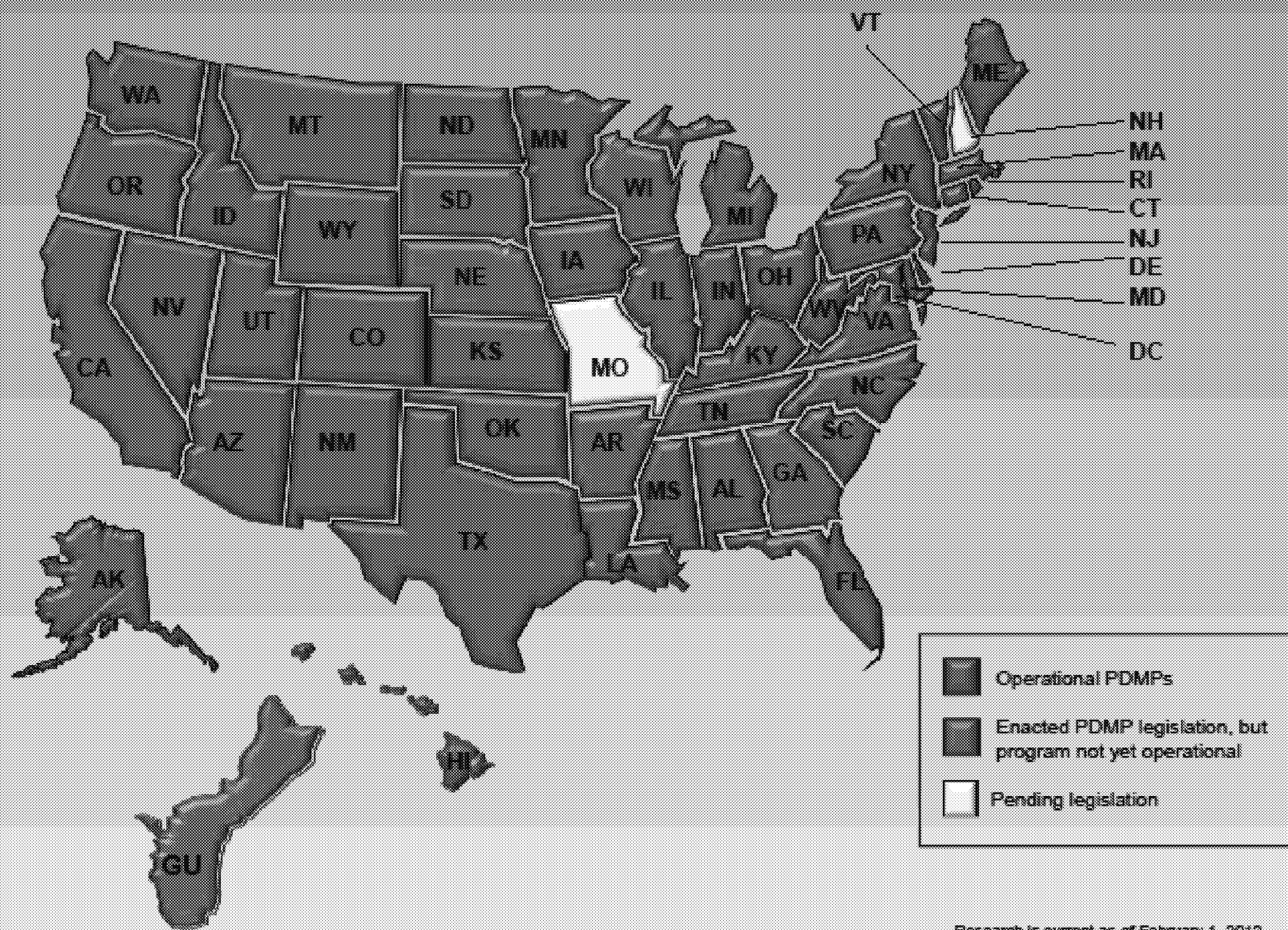


# Prescription Drug Monitoring Programs

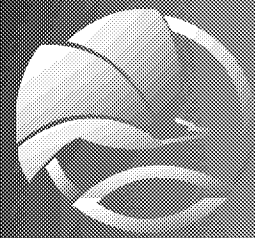




## Status of Prescription Drug Monitoring Programs (PDMPs)



Research is current as of February 1, 2012



# Diversion via the Internet



# Domestic 'Rx' Flow

1. Consumer in Montana orders hydrocodone on the Internet

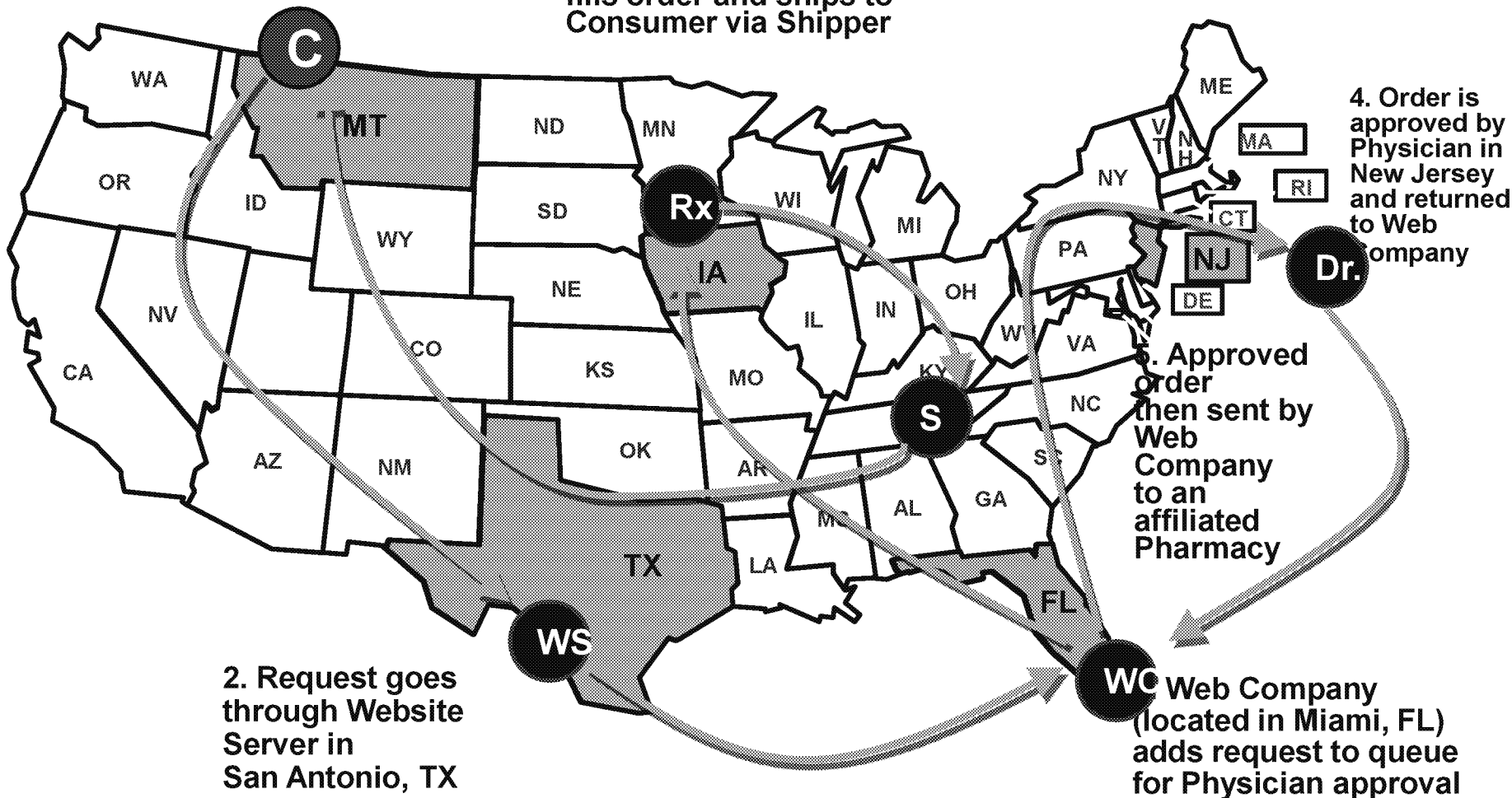
6. Pharmacy in Iowa fills order and ships to Consumer via Shipper

4. Order is approved by Physician in New Jersey and returned to Web company

5. Approved order then sent by Web Company to an affiliated Pharmacy

2. Request goes through Website Server in San Antonio, TX

3. Web Company (located in Miami, FL) adds request to queue for Physician approval



# New Felony Offense Internet Trafficking

- 21 USC 841(h)(1): It shall be unlawful for any person to knowingly or intentionally:
  - (A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this title; or
  - (B) aid or abet any violation in (A)

What has been the reaction????



# Per Se Violations

**Automatic Violation of the CSA if any of the following occurs:**

- No in-person medical evaluation by prescribing practitioner
- Online pharmacy not properly registered with modified registration.
- Website fails to display required information

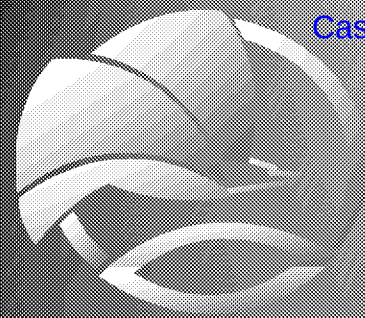
# Current CSA Registrant Population

**Total Population: 1,341,505**

➤ Practitioner	-	1,040,496
➤ Mid-Level Practitioner	-	170,115
➤ Pharmacy	-	65,946
➤ Hospital/Clinic	-	15,702
➤ Manufacturer	-	525
➤ Distributor	-	805
➤ Researcher	-	6,357
➤ Analytical Labs	-	1,504
➤ NTP	-	1,247
➤ ADS Machine	-	161

as of 1/21/2010





SOOOO...How many have  
applied for registration for  
Internet Pharmacy  
Operations?????

7

*What took the place of Internet  
Medical Care and Internet CS  
pharmaceutical Distribution?*





# Pain Clinics

# Medical Care ?

- Many of these clinics are prescription/dispensing mills.
- Minimal practitioner/patient interaction



# Checks and Balances Under the CSA

- Practitioners

*“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.”* (21 CFR § 1306.04(a))

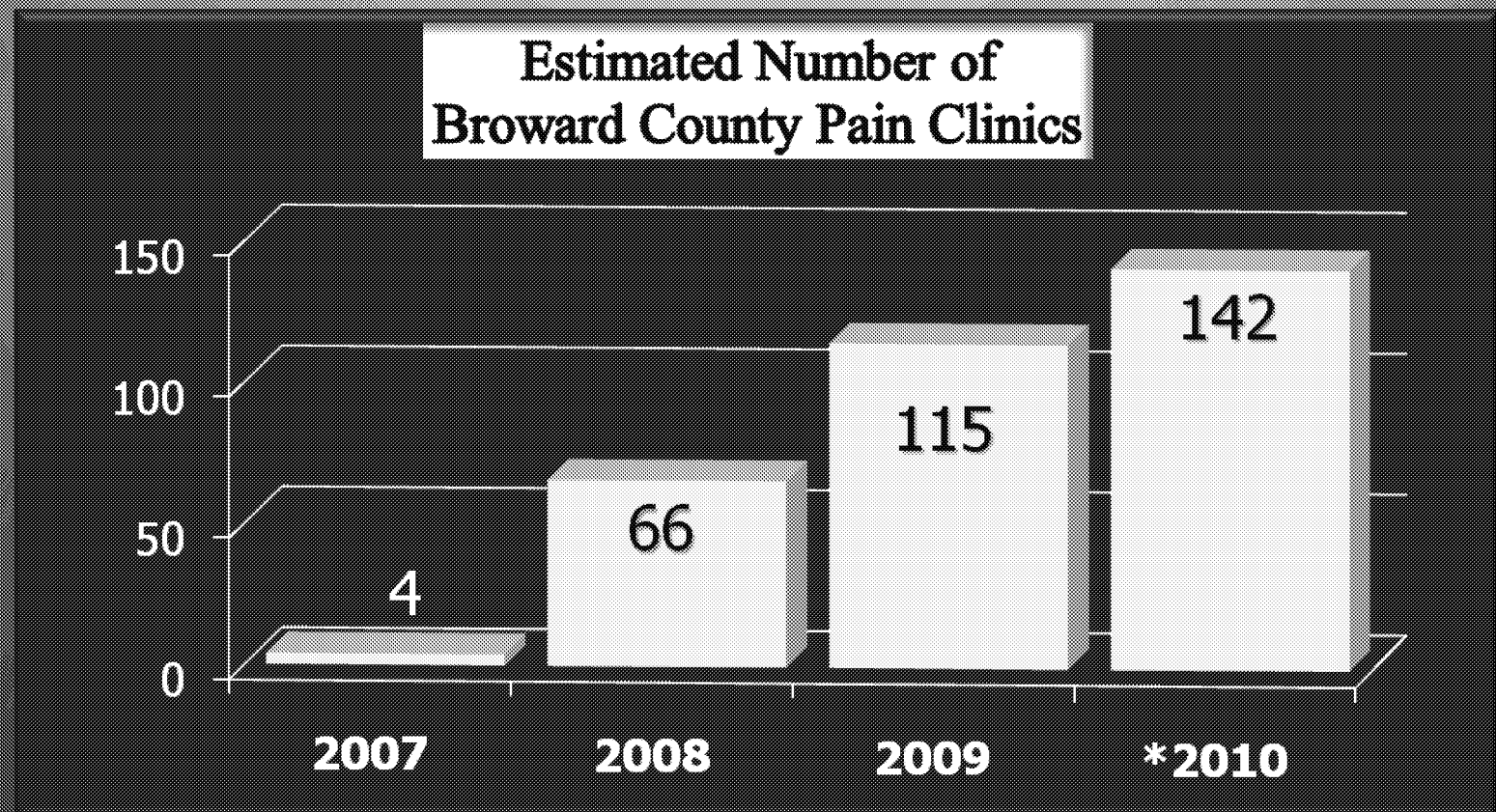
*United States v Moore* 423 US 122 (1975)

# Increased Law Enforcement Pressure

- Clinics migrating north and west
- Funded by owners in Florida



# Explosion of South Florida Pain Clinics



As of June 4, 2010, Florida has received 1,118 applications and has approved 1026

\*As of May 14, 2010, Broward 142; Miami-Dade 79; Palm Beach 111

# MIGRATION OF PAIN CLINICS





# MIGRATION OF PAIN CLINICS



# MIGRATION OF PAIN CLINICS





# MIGRATION OF PAIN CLINICS



# MIGRATION OF PAIN CLINICS





# MIGRATION OF PAIN CLINICS



# MIGRATION OF PAIN CLINICS





# MIGRATION OF PAIN CLINICS



# MIGRATION OF PAIN CLINICS

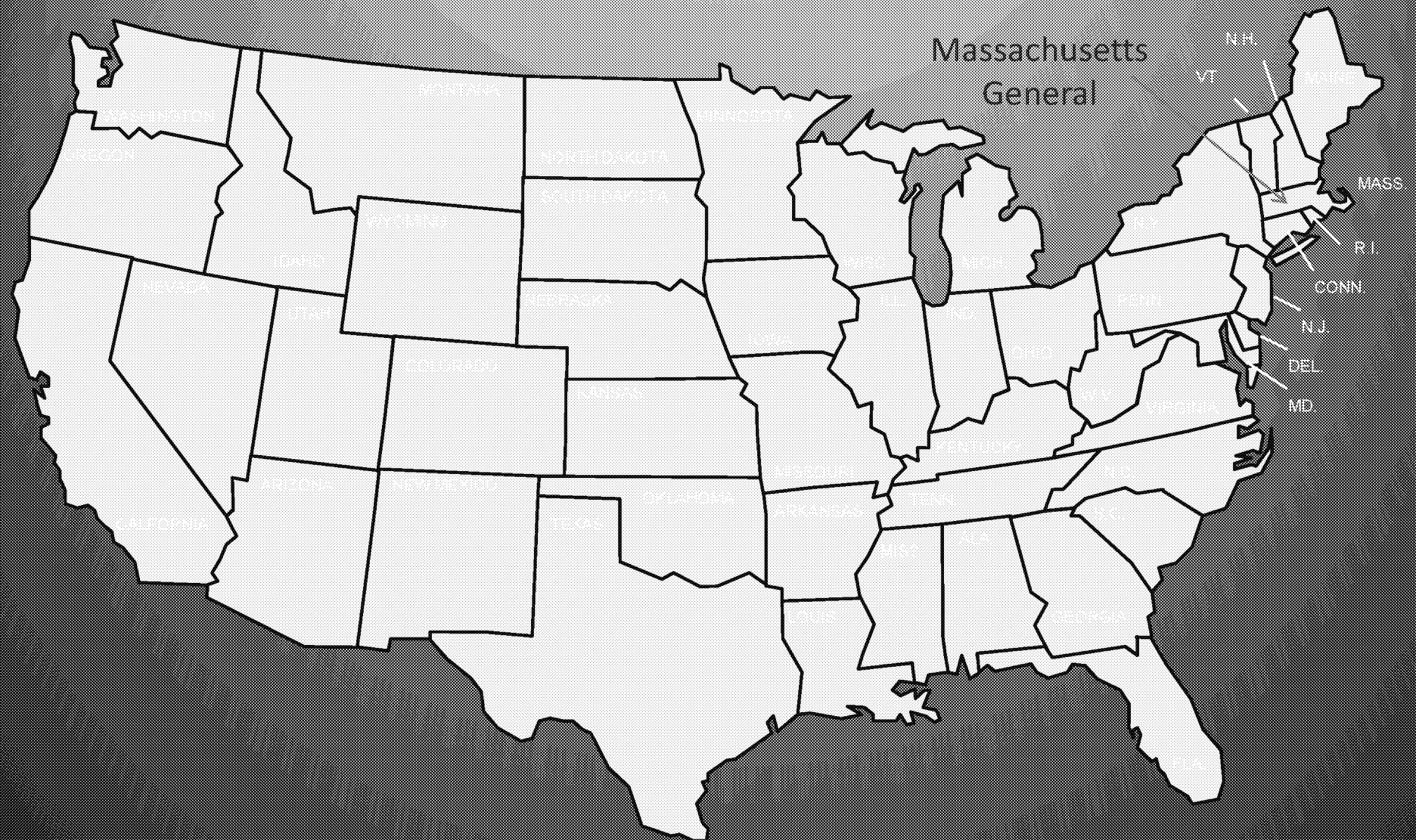




# 'The Florida Migration'

- Vast majority of 'patients' visiting Florida "pain clinics" come from out-of-state:
  - Georgia
  - Kentucky
  - Tennessee
  - Ohio
  - Massachusetts
  - New Jersey
  - North and South Carolina
  - Virginia
  - West Virginia

# THE MIGRATION

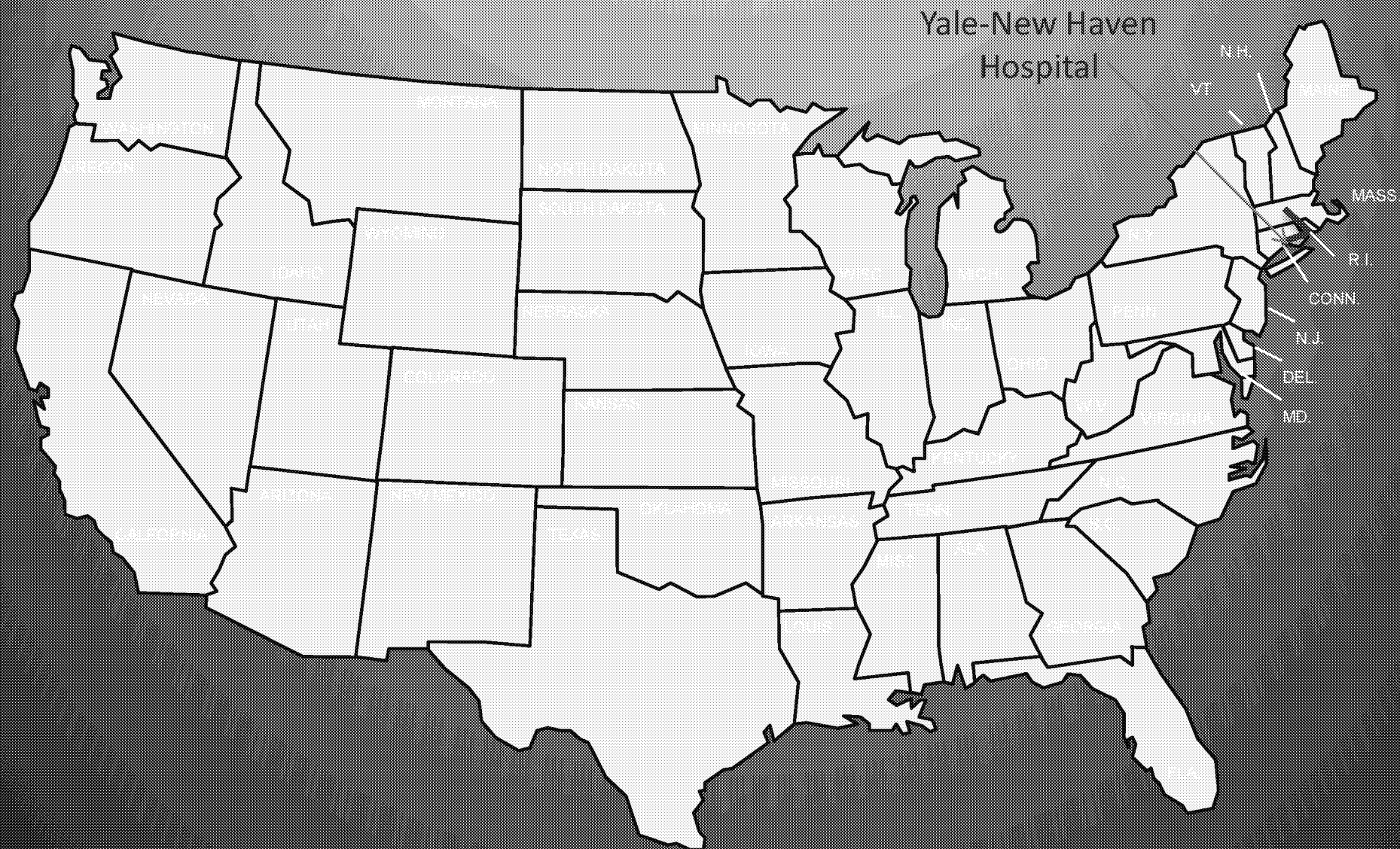




# THE MIGRATION



# THE MIGRATION





# THE MIGRATION

New York Presbyterian  
Hospital



# THE MIGRATION

Newark Beth-Israel  
Hospital





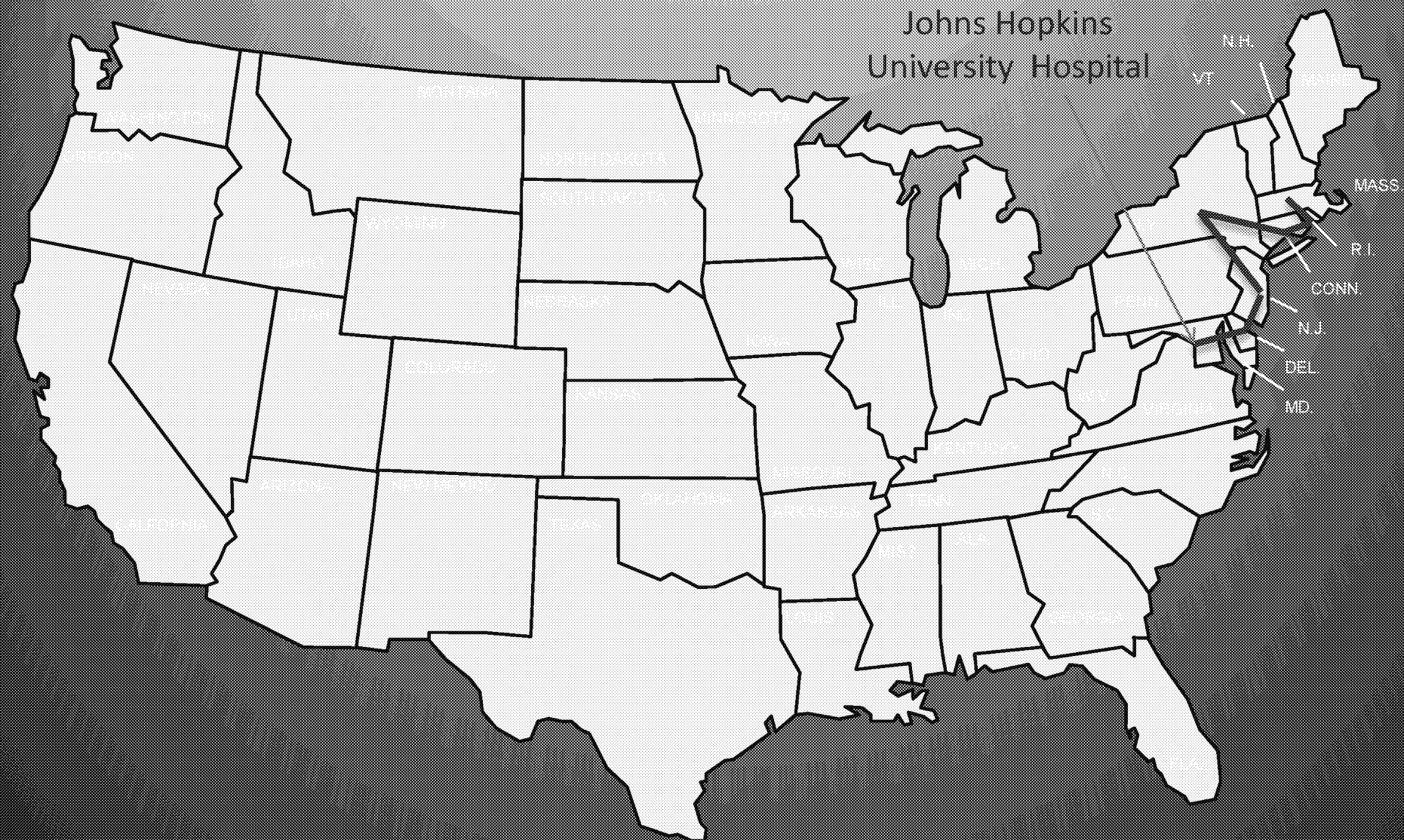
# THE MIGRATION

University of  
Pennsylvania  
Hospital



# THE MIGRATION

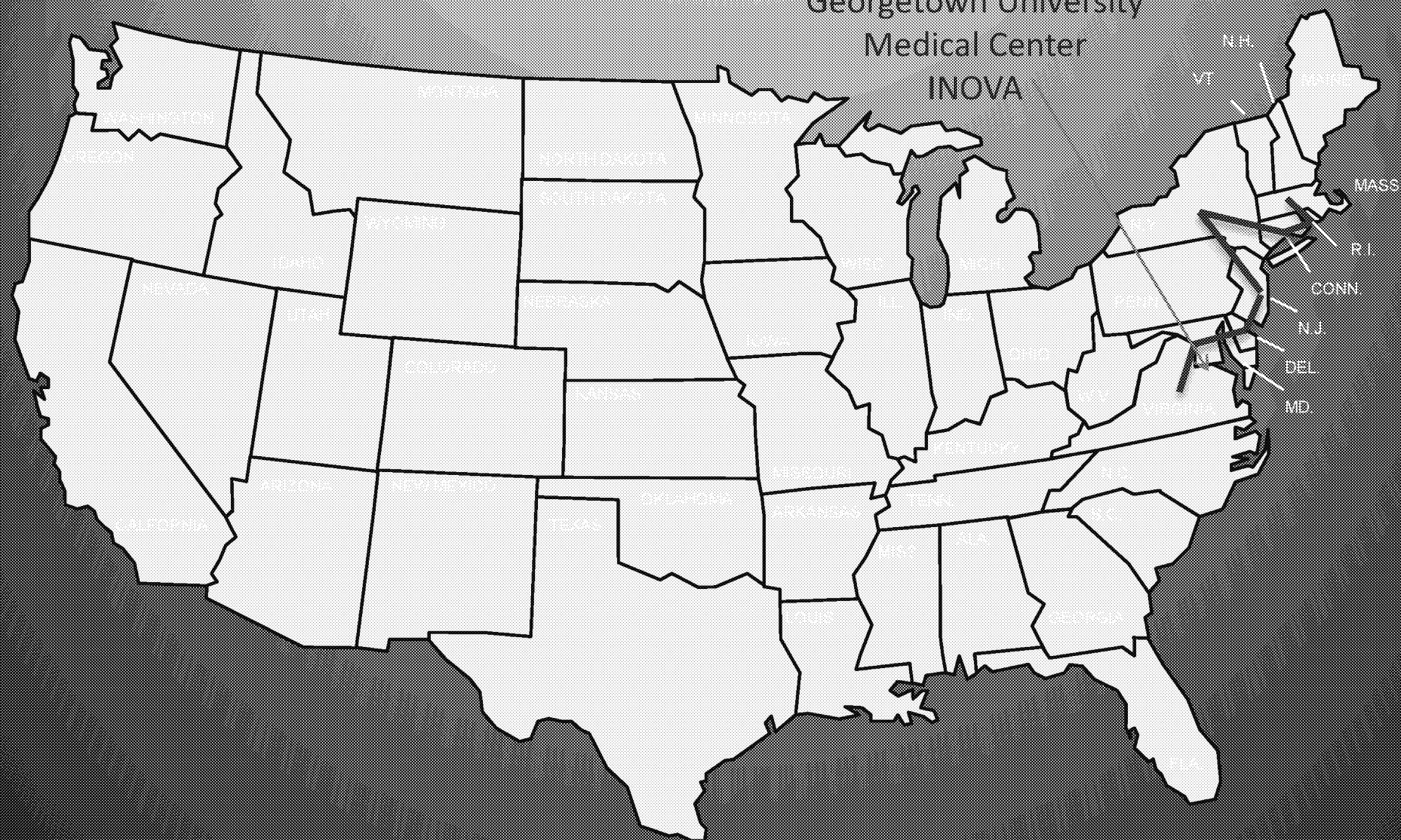
Johns Hopkins  
University Hospital





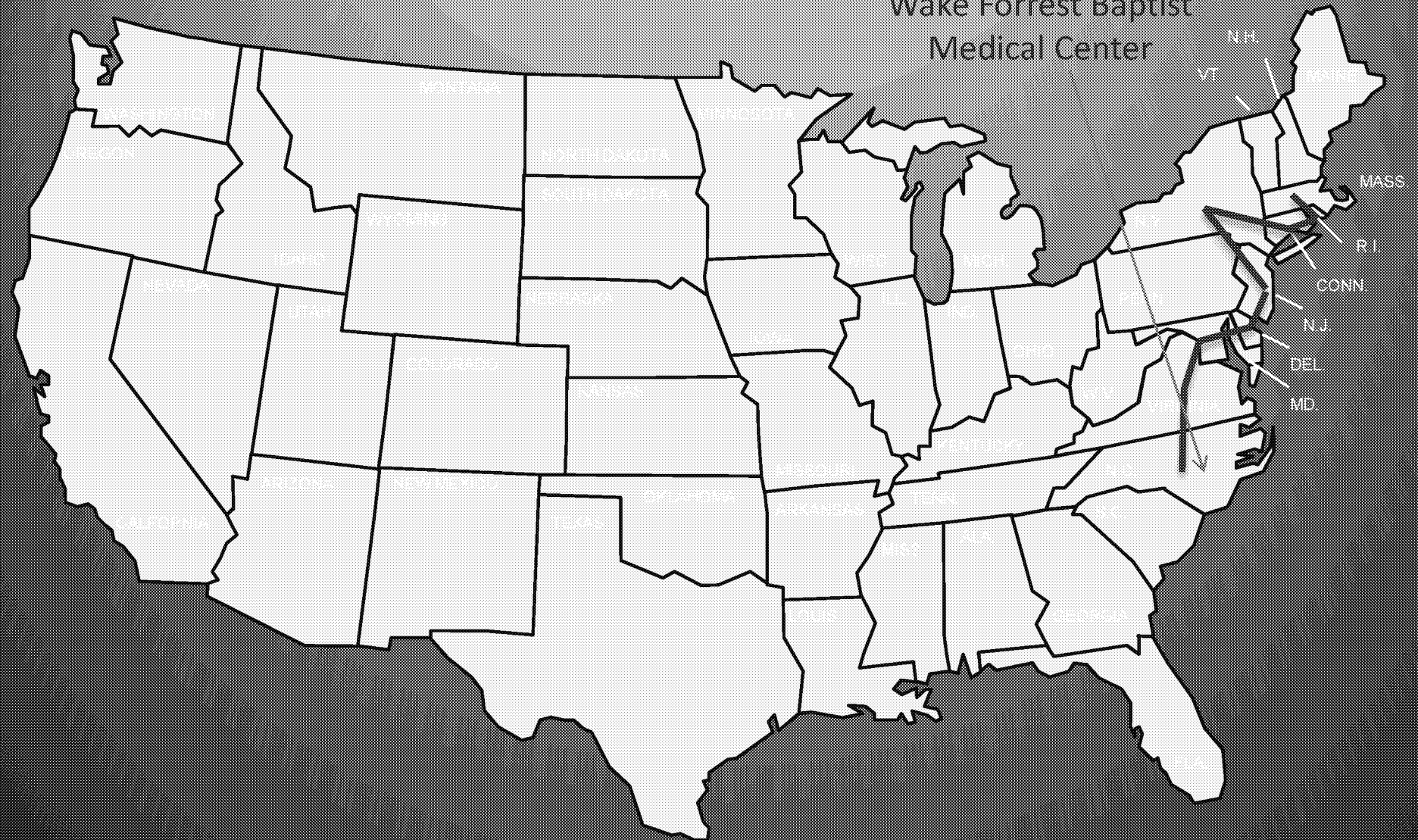
# THE MIGRATION

Georgetown University  
Medical Center  
INOVA



# THE MIGRATION

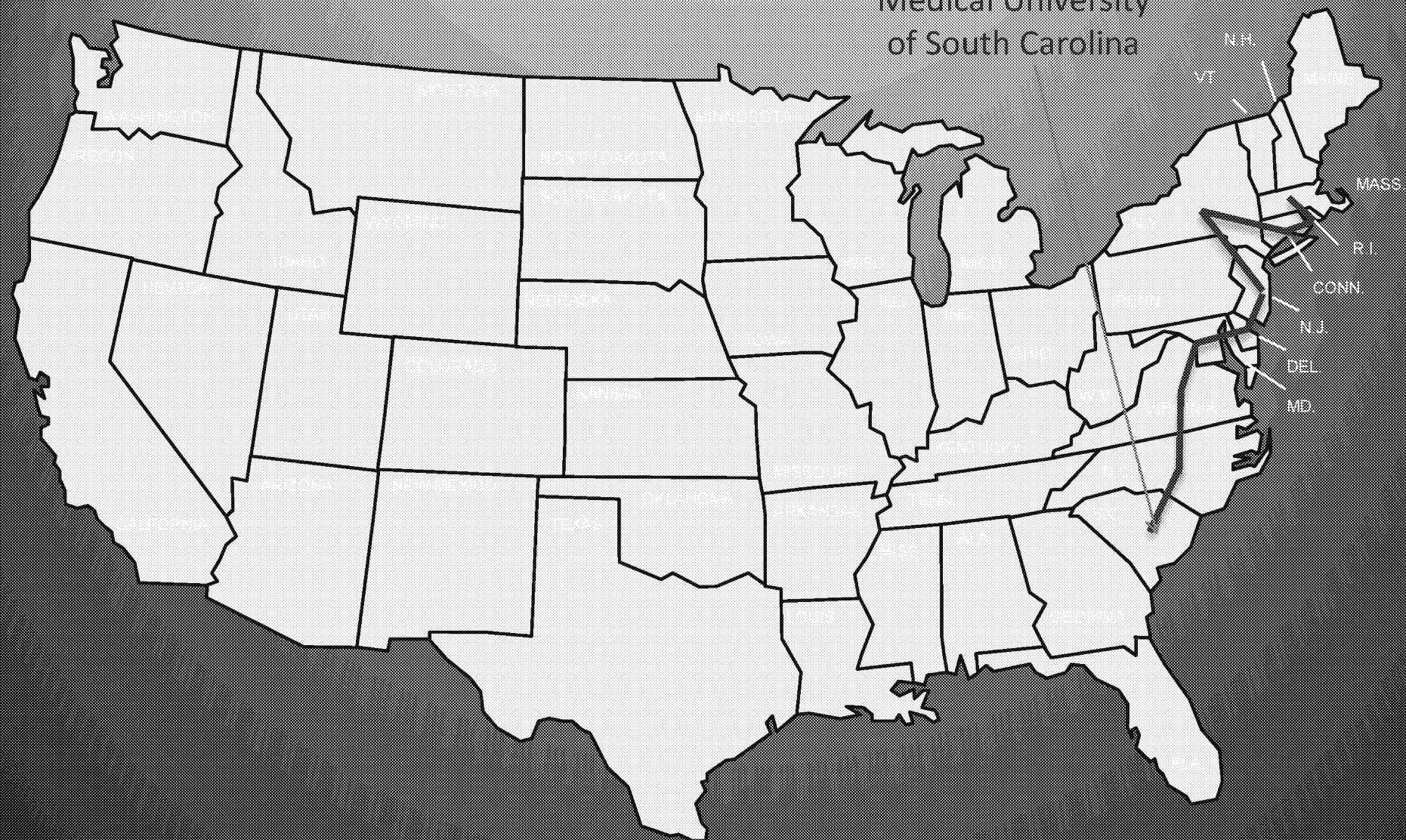
Wake Forrest Baptist  
Medical Center





# THE MIGRATION

Medical University  
of South Carolina



# THE MIGRATION

Emory University  
Hospital





# THE MIGRATION



# Drugs Prescribed

- A 'cocktail' of oxycodone and alprazolam (Xanax<sup>®</sup>)
- An average 'patient' receives prescriptions or medications in combination

Schedule II	Schedule III	Schedule IV
Oxycodone 15mg, 30mg	Vicodin (Hydrocodone)	Xanax (Alprazolam)
Roxicodone 15mg, 30mg	Lorcet	Valium (Diazepam)
Percocet	Lortab	
Percodan	Tylenol #3 (codeine)	
Demerol	Tylenol #4 (codeine)	
Methadone		



# Average Charges for a Clinic Visit

- Price varies if medication is dispensed or if customers receive prescriptions
- Some clinics advertise in alternative newspapers citing discounts for new patients such as 'buy one get one free' or "50% off with this ad"
- Typically, initial office visit is \$250; each subsequent visit is \$150 to \$200
- Average 120-180 30mg oxycodone tablets per visit

# Cost of Drugs

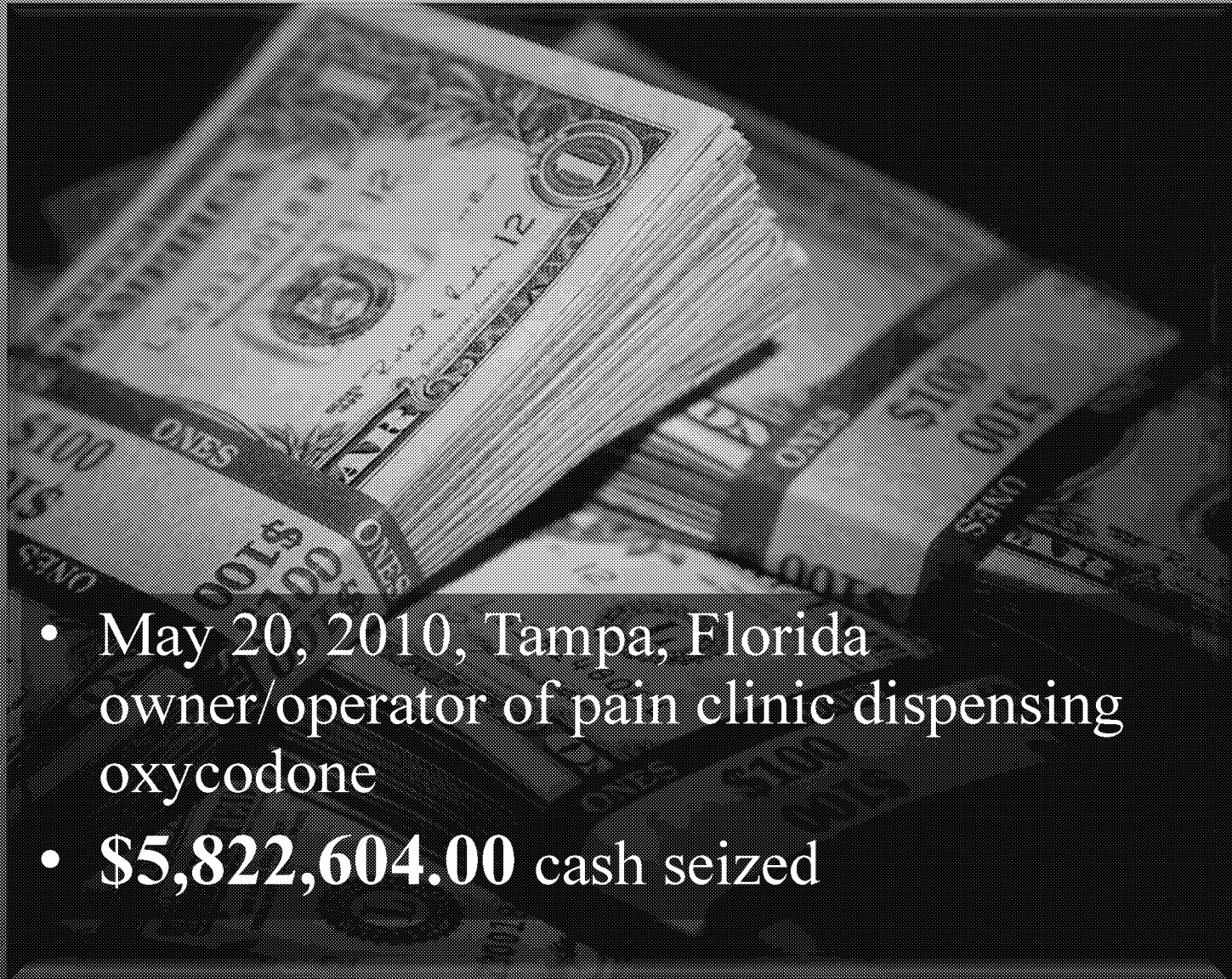
- The 'cocktail' prescriptions go for \$650 to \$1,000
- According to medical experts, most clinics do not require sufficient medical history and tests for proper prescribing of Schedule II substances
- Each oxycodone 30mg tablet costs \$1.75 to \$2.50 at the clinics
  - On the street in Florida, that pill can be re-sold for \$7 to \$15
  - Outside of Florida, it can be re-sold for \$25 to \$30 (\$1 per mg)





# Why is this happening?

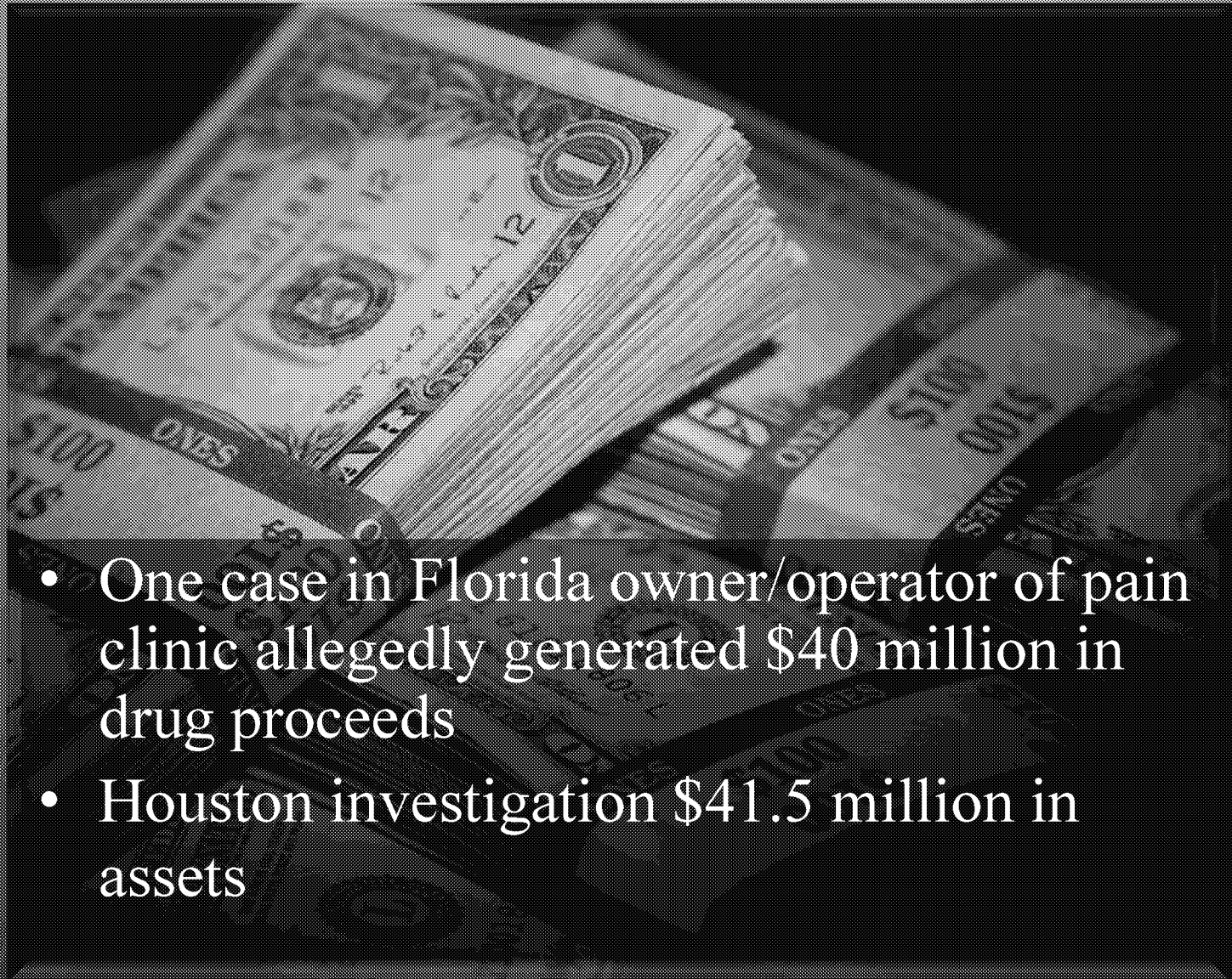
# What's the Profit?



- May 20, 2010, Tampa, Florida owner/operator of pain clinic dispensing oxycodone
- **\$5,822,604.00** cash seized

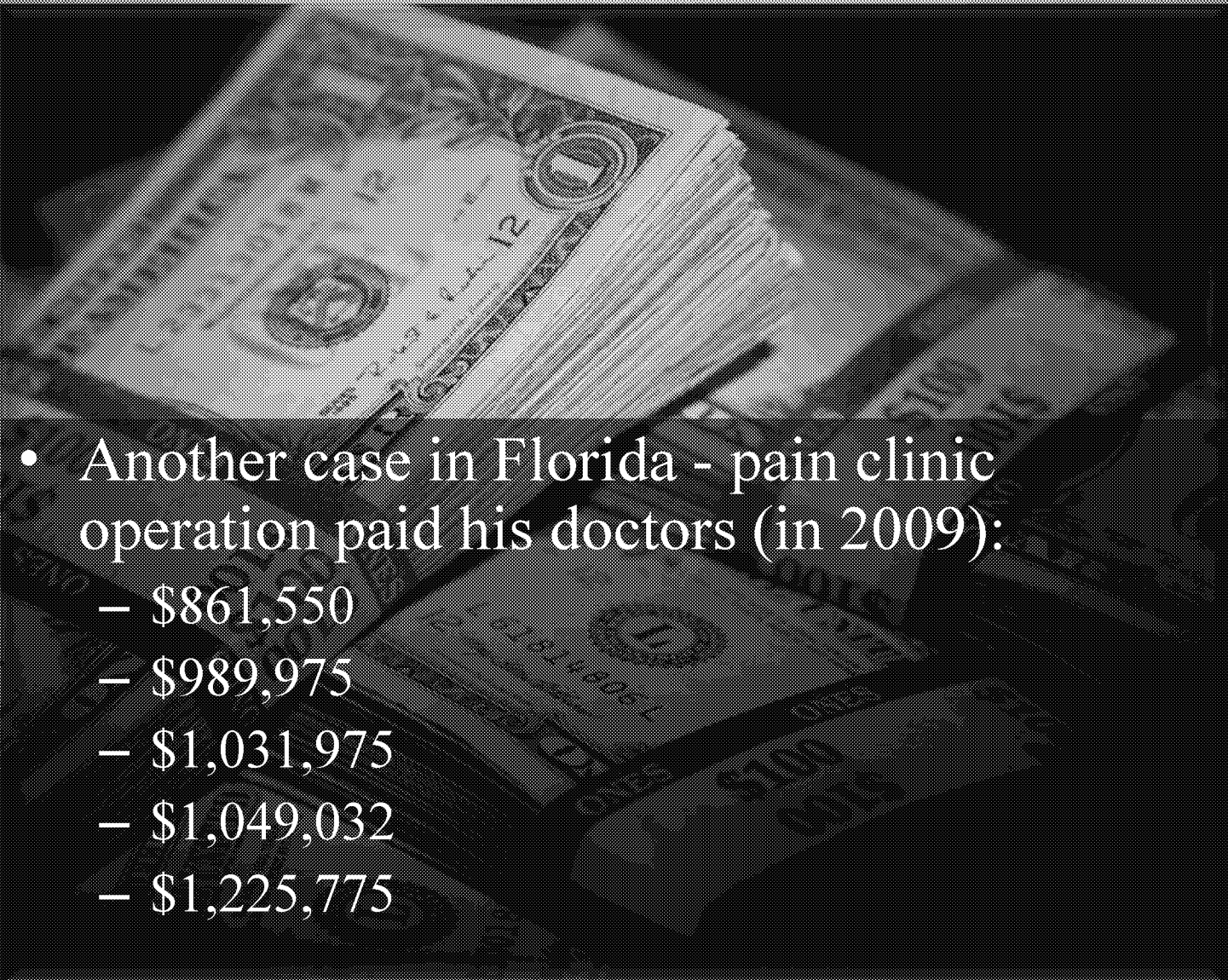


# What's the Profit?



- One case in Florida owner/operator of pain clinic allegedly generated \$40 million in drug proceeds
- Houston investigation \$41.5 million in assets

# What's the Profit?

- 
- Another case in Florida - pain clinic operation paid his doctors (in 2009):
    - \$861,550
    - \$989,975
    - \$1,031,975
    - \$1,049,032
    - \$1,225,775

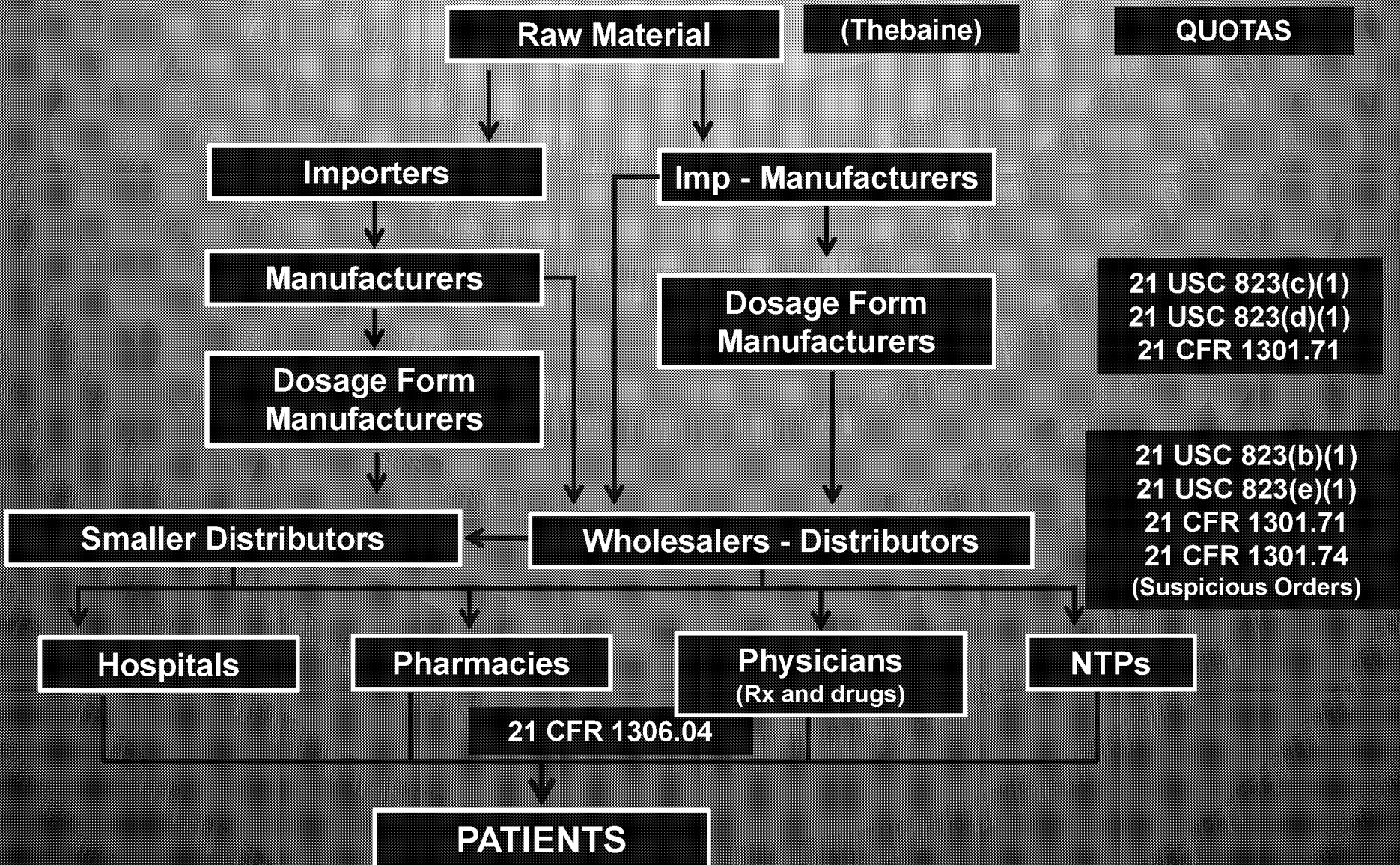


# DEA Distributor Initiative

## **August 2005 – Present:**

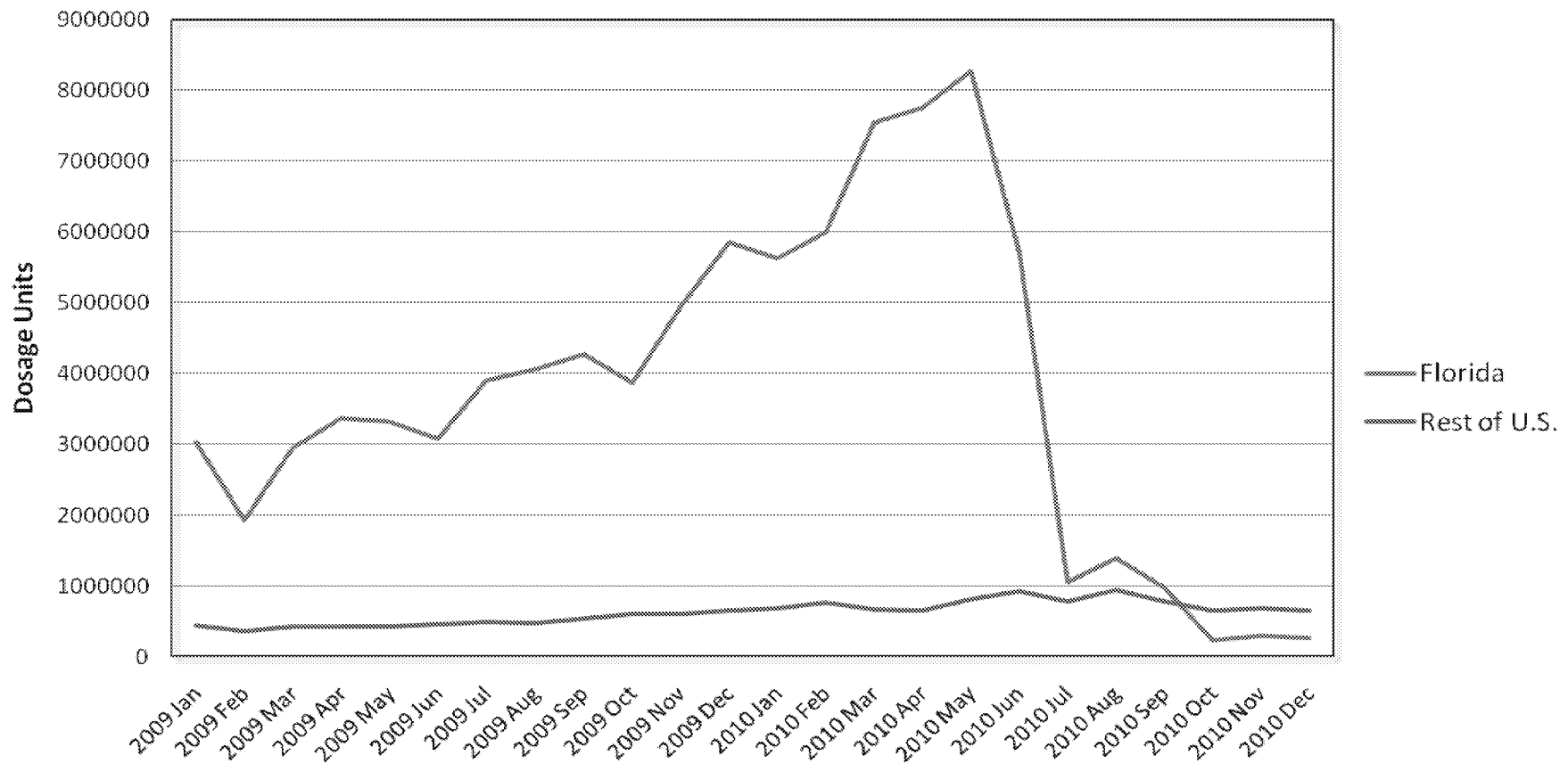
- **Briefings to 79 firms with 224 locations**
- **Examples of civil action against distributors:**
  - AmerisourceBergen,
  - Cardinal Health, \$34 million civil fine
  - McKesson, \$13.25 million civil fine
  - Harvard, \$6 million civil fine
- **Examples of suspension, surrender or revocation of DEA registration**
  - Keysource, loss of DEA registration
  - Sunrise, loss of DEA registration

# The Flow of Pharmaceuticals





## Monthly Oxycodone Sales to Practitioners 2009 - 2010



June 2010 DEA takes action against four wholesale distributors supplying doctors who were dispensing from rogue pain clinics.

# State of Florida Legislative Actions

## •Effective October 1, 2010

- Pain clinics are banned from advertising that they sell narcotics
- They can only dispense 72-hour supply of narcotics
- Prohibits the registration of pain clinics unless they are owned by physicians or licensed by non-physicians as a health care clinic

## •Effective July 1, 2011

- Clinics must turn over their supply of C-II and C-III controlled substances
- Clinics are no longer able to dispense these drugs
- Clinics cannot have ANY affiliation with a doctor that has lost a DEA number



# Reaction

- Shift from dispensing physicians to prescribing physicians
- New pharmacy applications in Florida increased dramatically in 2010

Clinic response to the Florida legislation  
prohibiting the sale of CS from pain clinics?

Buy Pharmacies!



## Beef prices on the way up

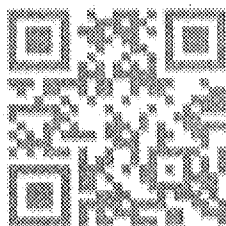
Low cattle supplies, strong foreign demand for U.S. beef help fuel price boost, 1B.

## Preserving pets after death growing popular as an option

Taxidermist Daniel Ross acknowledges it's a controversial topic, but says the owners "aren't weird, they just really love their pets." 3A.

## See news photos of the day on your smartphone

Scan with any QR reader or download the code scanner at scan.mobi. (Available on nearly every U.S. smartphone.)



Powered by



0 5

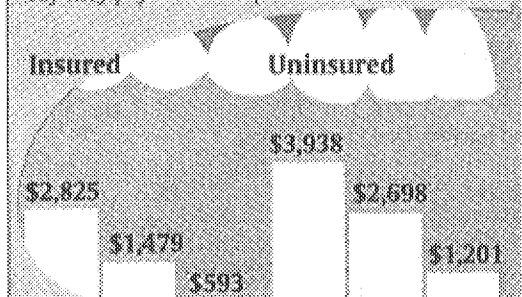
Crossword, Sudoku 5D  
Editorial/Forum 6-7A  
Market trends 6B  
Marketplace Today 5D  
State-by-state 7A  
TV listings 6D

©COPYRIGHT 2012 USA TODAY, a division of Gannett Co., Inc.  
Home Delivery, customer service  
1-800-872-0001  
www.usatoday.com

## USA TODAY Snapshots®

### A bite into dental costs

Average out-of-pocket costs Americans say they pay for dental procedures



Case: 1:17-md-02804-DAP Doc #: 2816-3 Filed: 10/14/19 Entered: 10/14/19 18:18 PageID #: 425154

can't cash period, or sell, promotion and a criminal record of pump-and-dump stock fraud. The former computer hacker is the principle figure behind Megaupload, which U.S. prosecutors charge was a global empire that reaped a mega-fortune from illegal digital distribution of movies, songs and other copyright works.

In a New Zealand jail awaiting extradition to the USA on charges of racketeering, money-

Dotcom's flamboyant life of parties and creating one of the Web's most popular and controversial sites — a site that came into the government's cross-hairs two years ago after a complaint from the Motion Picture Association of America.

In the days after Dotcom's arrest, the case has triggered an angry response from the hacker

Please see COVER STORY next page ►

# Dealers creative in oxycodone bid

## They try to open pharmacies after Florida targets 'pill mills'

By Donna Leinwand Leger  
USA TODAY

Drug dealers are finding creative ways around new laws that crack down on "pill mills" dispensing powerful painkillers such as oxycodone.

In Florida, hundreds of people tried to open pharmacies after the state barred doctors from dispensing the narcotics directly from their clinics and forced patients to fill their prescriptions at pharmacies. Others moved their operations to Georgia, state police and federal agents say.

"Traffickers adapt to situations," says Mark Trouville, special agent in charge of the Drug Enforcement Administration's field offices in Florida. "We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies."

Florida was the nation's center of prescription-painkiller distribution until the state enacted laws last year aimed at pill mills — clinics where doctors perform cursory examinations on people with dubious injuries and dispense addictive painkillers.

Since then, the number of Florida doctors among the nation's top 100 oxycodone-purchas-

A pharmacy must register with the DEA and be licensed by the state to dispense controlled substances, which include many drugs that require a doctor's prescription. The DEA can deny a registration if an applicant has been convicted of a drug-related crime or agents find a connection to a pill mill or other activity that poses a threat to public health and safety.

At least 37 pharmacy applicants withdrew their applications in 2011, Trouville says. "They feel the squeeze and move on," he says.

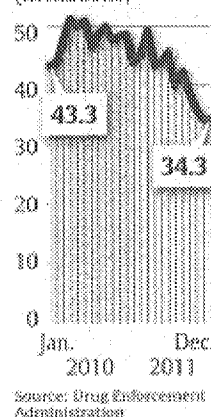
Still, questionable pharmacies are selling thousands of oxycodone and hydrocodone pills to people recruited by drug dealers to get prescriptions from pain clinics. "They're not selling Band-Aids and aspirin," Trouville says. "There's nothing but an empty room with a bulletproof window."

Pharmacy applicants turned down in Florida often try their luck in Georgia, says Rick Allen, director of the Georgia Drugs and Narcotics Agency. Of new non-chain drugstore applications, about 95% have some connection to Florida, he says.

"The people come completely out of left field without any pharmacy background and open a pharmacy in a sleazy strip mall right down the road from a pain clinic," Allen says. "You do a cursory background on them, and they're living in a doublewide in Pembroke Pines, Fla."

## Fewer pills

Number of oxycodone pills purchased by Florida pharmacies and practitioners:  
(in millions)



Source: Drug Enforcement Administration

By Julie Smiley, USA TODAY

ember; Gingrich fa Paul, who trai former Penn who also trail

"Gingrich's nomination is general elect Jacobs of the appeal to Tea him out of the

The Swing tion's most co Florida, Iowa shire, New M sylvania, Virg

The finding attacks on G by Romney a from Arizona majority lea speaker has c South Carolin the top of nat

In Florida, Romney led Sunday by 15

Gingrich bl aired by Rom policy of carpo said on Fox Ne

Romney, c Gingrich show his support ha

Voters in than Gingrich tics.

Nearly six i ity and leade have; 42% say percent call R say that of G Neither do whether they

# Who is Applying?

- An individual who is tied to Organized Crime
- An individual who works at Boston Market
- An individual whose father owns a pain clinic
- An individual whose mother works at a pain clinic
- An individual whose father is a doctor at a pain clinic
- An individual who is a bartender/exotic dancer
- An individual who is a truck driver
- An individual who is retired from the dry wall business
- An individual who is a secretary at a pain clinic
- An individual who runs a lawn care business



# Response

## Enforcement and Regulatory Action

- Investigating/Inspecting all new and renewal pharmacy applications submitted in Florida
- Investigating/Inspecting existing pharmacies registrations
- Results
  - Withdrawal of applications
  - Orders To Show Cause (OTSC) issued against applications
  - Immediate Suspension Orders (ISO) issued as appropriate

# The Last Line of Defense





# 21CFR 1306.04

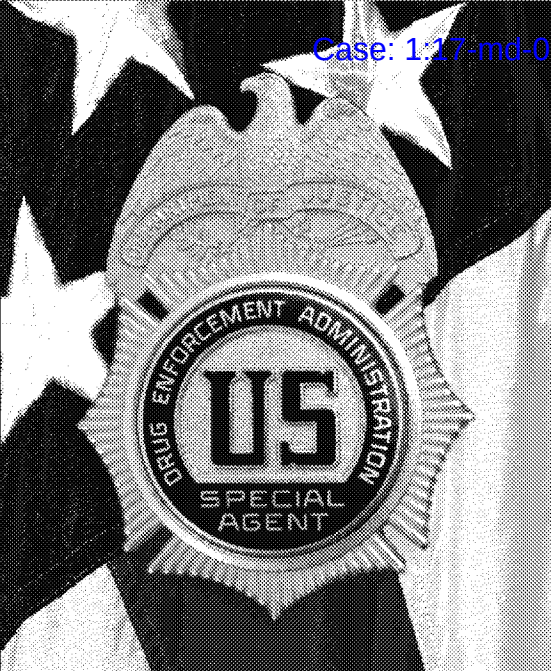
The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner , but a corresponding responsibility rests with the pharmacist who fills the prescription.

An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the act (21 USC 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

# Potential Red Flags

- many customers receiving the same combination of prescriptions
- many customers receiving the same strength of controlled substances;
- many customers paying cash for their prescriptions;
- many customers with the same diagnosis codes written on their prescriptions;
- individuals driving long distances to visit physicians and/or to fill prescriptions;
- customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and
- customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).





# Thank You!



# Questions